Compliance Management

Design of a system monitoring local implementation of Global Best Practices and Standards

Stefan Fransen – Twente University 2013

Preface

This thesis was written as part of my bachelor course of Industrial Engineering & Management at Twente University. This report shows the results of my research at a Dutch company in food industry. The main focus of the research is the "Deviation Management Procedure" in the production and laboratory environments within the company, which is a form of Compliance Management.

Due to the sensitivity of the topic to the company, various details could not be published. This version is the public version of the report, which may miss some details sensitive to the company. Next to details, the name of the company this research took place at has been replaced with a anonymous 'the company', with the global organization this company is part of being of is referred to as 'the global organization'.

I arrived at the position after I applied for its vacancy and got selected after an interview. For the department I was the first intern ever, I'd like to thank my attendant for all arrangements made and support/feedback during my time at the company

In this report the results of my main research are laid out, but during my time at the company I also did several other smaller projects; on (global) kpi representation and a dashboard in the main process control room. I'd like to thank the organization for giving me the opportunity to work close to the fire and give me an insight in both performance measurement for the higher levels of management, as well as on operator level. After completion of this report I stayed with the company part time to further improve the product I developed during the internship, and roll out the accompanying procedure to the Engineering department as well.

Abstract

Since six years, when the company was taken over by a much larger conglomerate, a lot had changed to the company. Slowly it had encorporated working methods and technical standards, a process still underway in the time my research took place. My research actually focussed on the implementation of the so-called Deviation Management Procedure, the prescribed working methods in case of noncompliance; in other words, compliance management.

In the early phase of my thesis, I found that the implementation of this Deviation Management Procedure (DMP) was only partial: business processes were not fully adjusted to the working methods and reporting style required and there was no workflow modelled of the process. For managers, there was insufficient management information available to control the process.

Using global guidelines and specialists' and manager's insights I created workflows for the different actors and different types of deviations, set deadlines for process steps and classified all current cases. Using this information I set up a monthly update, with deadlines and steps to take on all current active cases. I worked mostly with the Production department in this period, as they were facing an external Audit during the internship period, pressuring them in getting all processes compliant.

A prototype of the to be implemented system was created based on Excel (with VBA to create necessary functionaly) in parallel with a selection process of the final system. Using the SMART rating technique multi-criteria analysis was performed on seven possible implementation routes. Based on this analysis it was decided that the developed prototype would be built into a fully operational system based mainly on cost and availability criteria.

During the second half of the internship period, using a participative design process we tested the new procedures and the IT system, based on an evolving prototype. In three steps improvements were tested and feedback was received and processed. This report contains further recommendations for an integrated system for compliance management organized globally. During the latter part of the project, the Laboratory and Packaging departments were catching up on a backlog of internal audits, leading to both departments to get acquainted with the new working methods as well.

After the development period, the system continues to be used. Employees involved expressed that they value the extra overview the system gives on a monthly basis to better keep track of progress made, or lack thereof. This is now also visible for the cases waiting for approval, as progress is checked systematically, there is now an overview of what cases lie waiting at the European headquarters extended amounts of time.

On the administrative side, in the Quality Assurance department, the implementation of the system lead to an improved awareness of other departments' performance on this issue, and relieved employees of much handwork related to keeping track of progress of filed cases.

A secondary outcome of this research is a new kpi 'adjusted compliance', measuring efforts in closing the compliance gap as well as the actual compliance. For managers a dashboard was created

that allowed them to see progress made in the different steps of the improvement process, by graphically displaying the progress in the different elements the performance indicator. Finally also a customizable waterfall graph was produced for the companies' Technical Director, enabling to graphically display compliance improvement over time against required expenses and investments.

Parts of programming code produced during this thesis was also used in other parts of the company for easing the transition between filled in document templates via a structured list to performance dashboards.

Finally recommendations where made to research the possibilities to roll out a system for handling the deviation management procedure work flow to other plants within the organization.

Contents

Glossary

CAPEX	Capital Expenditures, 'investment' falling outside of regular budget
Concession	One-batch allowance to produce outside of specifications.
DMP	Deviation Management Procedure
Injunction	Filed deviation, valid for >1 year and/or CAPEX required but not yet packaged.
OPEX	Operational Expenditures, (recurring) expenditures related to operations
Permit	Filed deviation, valid for <1 year, no CAPEX
QA	Quality Assurance (department)
QC	Quality Control (the laboratory)

1. Problem Statement, Methodoloy & Structure

This report describes the route taken towards an improved implementation of the 'Deviation Management Producedure' within the company. In this chapter a short introduction to the problem will be given, followed by the defined problem statement, used methodology and the subsequent structure of the entire report.

1.1 Introduction

When the company was taken over six years ago new knowledge and best practices were brought into the organization. These are bundled into three sets of documents, focused on Production, Packaging and Microbiology (Quality Control). Each set of documents contains about 500-600 pages of background information, technical specifications and best practices for the respective areas and is updated regularly.

Over the last five years, the company has worked towards implementing these standards. Every department is obliged to follow a 2-year cycle of internal audits, covering all aspects of the relevant Global Standard. These cyles are part of a 6-year cycle, of which the company is now in the 2nd cycle (3rd year).

Whenever a deviation from a standard is detected during an Audit or during regular production, a formal report is produced containing the problem (degree of deviation from a given standard) and how this deviation can be addressed. Easy to solve problems, which require no capital investment and can be solved internally within one year are filed as 'Permit', while more complex problems requiring either more time or a capital expense are filed as 'Injunction'. While the company can grant itself a Permit, it needs permission from the European Headquarters ('Hub') to satisfy an Injunction request.

The company however faces some problems while handling Permit and Injunction requests, which made the Manager of the Quality department, to file an Internship / Trainee vacancy. As one of the responders on this vacancy, I was ultimately allowed to investigate these issues the company faced. The results of this research and the consecutive implementation of a small-scale information system can be found in this report.

During the first weeks at the company I decided to investigate whether the problem perceived would match with the actual problem they faced. Even so; the company already had a solution in mind, namely 'to develop and implement a system to control deviations within the entire production chain'. As this is a rather broad statement, some preliminary research was required.

During this investigation, the following was found: Implementation of the system of filing and administering Permit / Injunction requests is incomplete. There is no one clearly accountable for the process, administration is incomplete and progress is insufficiently monitored. There is no central report available on current cases. It is unclear whether Internal Audits lead to the actual filing of deviation reports, where necessary.

Within the three affected departments there is a clear demand for a system in which tasks and responsibilities relevant to the process are defined, progress can be monitored systematically and performance can be measured from. Furthermore it is important to acquire and organize management information relevant to the cases and present it in a clear and structured way. This information needs to support management decisions on investments, budgeting and will impact KPI's (e.g. efficiency, losses, quality, durability)

1.2 Problem Statement

The following problem statement forms the main focus of this research:
How can the compliance management process within the 'Operational Company' of the company be structured?
Answering this problem statement will enable the actual implementation of a system addressing the problems the company faces. In order to answer this question, several sub questions need to be answered first:

1. *Which documentation/regulations are currently in place regarding compliance management?*
2. *What problems does the company face with the current implementation of compliance management?*
3. *How do the existing regulations affect the implementation of a solution?*
4. *Which are the technological and financial limitations for a solution?*
5. *To which internal requirements must a solution comply?*
6. *What is a sound method to use when implementing a solution?*
7. *Which are leading parameters when designing solutions?*
8. *Which are leading criteria when selecting a solution?*
9. *What solutions are relevant?*
10. *What are pro's and cons of formulated solutions?*
11. *What choice of formulated solutions is appropriate?*
12. *How should the chosen solutions be implemented?*

The answers to these sub questions are covered in chapter 3 throuh 5. For a list of brief answers of the first eight questions, see Appendix A. Questions 8 through 11 are covered in paragraph 4.3, Question 12 is covered in chapter 5.

1.3 Research Methodology

In selecting the problem statement and during the rest of my thesis, I used the Managerial Problem-Solving Method (MPSM) by Heerkens as a guideline. The MPSM defines the following process steps, which can be found in different chapters in this report:
1. Identification of problem
2. Formulation of problem-solving method
3. Problem analysis
4. Formulation of alternative solutions
5. Decision
6. Implementation
7. Evaluation / feedback

(Heerkens, 1997)

For the first part of this research a case study was performed within the company, of which the conclusions can be found in the introduction of the report and in more detail in chapter 5. As a case study will give an in-depth view of a limited set of objects/processes in a short timeframe, it fitted the requirements best (Verschuren, 2003).

By creating a problem bundle with the found problems, root causes of the problem have been defined, for which solutions were generated. For the implementation process a parallel participative design process was used (in conjunction with the decision making process using SMART) in which the people who would work with the system (specialists from the three different involved departments) were involved in several stages during the development process. SMART (using a Multi Attribute Value function) was used over other techniques like AHP (analytic hierarchy process) due to personal preference by the researcher. Belton shows that both methods give comparable results (Belton, 1986).

The reason for choosing a participative design approach is the almost timeless “people problem” in IT implementation. Poor acceptance and low usage of systems are mentioned as results of not involving users in systems design (Ackoff, 1967) (Dickson, 1984).

As the involvement of users in the design process bears relatively high costs, much research has been done on its effects on the process. According to Olson & Ives (1981) there is a complex relationship between the type and degree of user involvement and other organizational and individual factors; which affects both user satisfaction with and usage of the resulting systems (Olson, 1981).

With a participative design approach -when done right- good results can be obtained. Anderson defines seven managerial questions to be answered before endeauvouring into a participative design process. These questions encompass:

- the knowledge/experience level of the user with the technology
- how structured the application of the system is and the amount of exceptions it entails
- How much change is introduced by the system
- Skill and commitedness of the project leader; support/endorsement by management
- Willingness of the designer to give the user substantial influence in directions
- Willingness of the user to be involved

(Anderson, 1985).

A full list of these questions and its answers can be found in appendix A.

Although the fundamentals of participative design, (or "participatory design", as it is more often refered to in recent years) dates back about forty years, nowadays it is still a usually successful practice performed in a wide variety of industries. Examples in literature are found employing the practice on clinical staff on an operating room scheduler and users from public e-services. Expectations are that the participative design approach will also work well withing the company subject to the research. (Karlsson, 2012) (Hasvold, 2011).

Below an overview of the entire process is displayed with a global time frame. In four one-month cycles the system was developed. After an initial set of interviews with managers and specialists involved, monthly a new version of the system as released and a survey took place to enquire actors on further required improvement. In Chapter 5.2 these evaluations are covered in detail.

[removed from public version of the report]

Figure 1: Overview of the applied participatory design process

1.4 Structure of this report

This report is structured in the following way:
Chapter 1 covers some background information on the company and gives the problem description and research methodologies used. The current administrative and Audit procedures are described in chapters 3, as well as the problem analysis.
The selection of a solution is covered in chapter 4; its implementation, evaluation and (possible) improvement can be found in chapter 5.
Conclusions and recommendations can be found in the last chapter: Chapter 6.

2. Company description

[removed from the public version of the report]

3. Problem Analysis of the current implementation of the Deviation Management Procedure

This chapter gives some insight into the current Deviation Management Procedure within the entire organization including some examples of the differen kinds of devation (removed in this public version), problems found in the implementation of the procedure within the company and determined root causes to the perceived problems.

3.1 Introduction & Definition

Within the global organization, the Deviation Management Procedure (DMP) exists to manage situations where either product, work method or equipment fails to meet specifications. The purpose of the DMP is defined as: *"…to formally recognise deviations, and to ensure there is a formal record of the appropriate management decisions taken with regard to non-conforming materials, processes and product.*"

The DMP defines three types of situations, for which a different type of approval and accompanying form are required. The following diagram states those different types. The research focuses mostly on 'Permits' and 'Injunctions'

[removed from the public version of the report]

Table 1: DMP file types (from internal document)

The set up procedures by the global organization seem to have found their origin, at least in their definitions, in the medical sciences. Published research on the topic "deviation management" has mainly taken place in the pharmaceutical industry.

Just as in these industries; the process of making the product in this company is very susceptible for external influence; a high quality can only be assured if the process is controlled precisely. The DMP as defined by the global organization has a great resemblance with deviation management procedures like the one described by Boltic, in which is described that all deviations in the process should be addressed and resolved quickly and analyzing information generated with the DMP is important (Boltic, 2010)

What is defined as "Deviation Management" by the global organization can generally be considered to be Compliance Management. It matches closely with the definition of Yip et al: *"the process of assessing an organizational adherence to a set of requirements and expectations."* In the execution of the DMP within the company, the following quote of the same author fits the actual situation well: *"[…] it is a continual, manual and labor intensive process that is proved to be of great challenge for many organizations. CM affects almost every aspect of an organization and is in nature a complex problem due to voluminous knowledge and data involved."* (Yip, 2007)

3.2 Examples of the different types of deviations

3.2.1 Concession

[removed from the public version of the report]

3.2.2 Permit

[removed from the public version of the report]

3.2.2 Injunction 2

[removed from the public version of the report]

3.2.3 Injunction 1

[removed from the public version of the report]

3.3 Workflow

The Deviation Management Procedure is based on Internal Audits (see 3.3), leading to found deviations. These deviations need to be classified, determining whether a so called Permit or Injunction procedure needs to be started. The two main parameters used when classifying deviations are the amount of time needed to resolve the deviation (less or more then one year) and whether investments (CAPEX) are needed. The following flowchart models the Auditing and Classification process. Types of classifications are covered more extensively later in this report. After classification and writing a Permit / Injunction request, the request is processed by Administration (see 3.3). This is a graphical overview of the workflow of the process:

[removed from the public version of the report]

3.4 Audits

There are two types of Audits defined within the global organization, internal and external. Departments within the company are required to do a self-audit for every part of their department once every two years. Those are part of a global 6-year audit cyle, of which the company is now in phase 2 (year 3). Internal Audits are spread over this period to minimise stress on either the audit schedule or the departments specialists charged with solving any found deviation.

Each department is by itself responsible for setting up an auditing schedule and appointing auditors to given audits. The QA department monitors the audit planning and signals departments if they are falling behind schedule.

Audits are organized around a coherent group of parameters; in the packaging department an Audit may entail an entire filling line, whereas in Production it may be specific part of the production process.

During my period with the, the Production department was faced with an external Audit. The schedule for external Audits at the company is still being established (as it only recently joined the global organization's 'family'), but the general practice within the global organization is that external Audits are performed every second year for the different functions. The Packaging department receives an external Audit after my internship period has ended.

This Audit for the Production department made it focus on doing their own internal Audits as thorough as possible, leading to plenty of Permit and Injunction requests. These gave a nice, fresh set of cases to work with during my research. For the other departments the priority for internal Audits may have been lower, due to less pressure of an external Audit (more on this later in the report).

The Auditing process was explicitly not a part of the assignment by the company. Therefore, no workflows of that process have been developed on my part. As Audits are closely related to the DMP, references to them can be found in the updated procedure (See chapter 4).

3.5 Administrative process

Currently the administrative process supporting the Deviation Management procedures (including Permit / Injunction reports) can be best described as a paper process. To some degree information is stored digitally, but only after information has circulated for a while in paper documents.

Information is created after performing an Audit in either the Production or Packaging departments, or the laboratory. Whenever a deviation is recorded, a Permit or Injunction report has to be filed. Currently these documents are typed on a PC (excel template), after which the document is printed. The files are reviewed on paper by the Technical Director (TD) who has to sign them or give feedback. After signing (or a revision based on the feedback, followed by signing), the document is sent to the Quality Assurance (QA) department, where the documents are filed in a ring binder folder, one for every fiscal year. A selection of the documents is typed into an (excel) list, which is sent to the Europe head office twice a year. All physical documents also get scanned or copied and sent to the headquarters.

Although files are ordered in the folders (by month), there is no further overview of all documents, neither is there any index or other tool so quickly find a certain report or to produce an overview. There is a Sharepoint site available where the reports were stored digitally in original form, although this source is incomplete; not all reports are stored there. Furthermore, reviewing the actual paper files revealed that a large portion of them were not correctly filed (important information missing).

The Excel list maintained for the head office is the only tool to give some (management) information, i.e. the amount deviations currently recorded. This file however, is incomplete. Over the last years there had been some changes to the template of the to-be-filed documents. Several people in the organization did not update their templates currently, so even recently new files all have different templates used. Some versions only differ a bit on layout, but the information contained in the reports had also changed, leading to different reports, depending on the writer.

During the first and part of my second month at the company, I analysed the processes described in Chapter 2 [not present in this public version] and found various problems within the organization. This chapter elaborates on these problems already briefly mentioned in the introduction. Official documentation regarding the process was studied, as well as all current and past cases. Interviews took place with all three managers working with the procedure, as well as six specialist that were involved. In these interviews the actors were asked how (well) the procedure was implemented and what could be inproved in it. In appendix I the questions list can be looked up. The findings of this investigation are displayed in the following paragraph.

3.6 Problems found

In this paragraph the six most important problems that were found will be listed.

3.6.1 Administration is incomplete

When comparing the digital with the paper administration, it was found that not all cases had been registered digitally. While not very problematic in itself (cases had been sent in copied form to the headquarters too), it did mean there was no complete overview of all active cases.

3.6.2 Progress is insufficiently monitored

During the process of updating the digital administration it became clear that a multitude of cases were expired, but there was no sign the underlying problem had been fixed. According to the procedure an 'Injunction' procedure would have been started, but this was not always the case. It turned out that the various people working with Permits / Injunctions in the different departments did not and could not get any progress information.

3.6.3 There is no central report available on current cases

On management level there was no report available to display where any managers department would stand regarding the permit/injunction process, making it a difficult process to manage and something that easily would slip off the radar. One department was even unaware of the existence of some of the (expired) Permits, as the preson filing them a few years ago had left his position since.

3.6.4 Unclear whether Internal Audits lead to the actual filing of deviation reports

In the current implementation of the Auditing/reporting procedures there was no check on whether a finding reported in an Audit would actually lead to the filing of a P/I report. The associated key performance indicator (KPI) with the process would only measure the compliance with the standards, but no points were rewareded for describing the compliance gap.

3.6.5 There is no one clearly accountable for the process

Over the past few years, responsibility for the administration of the cases had shifted several times between people, leading to a bad overview and management of the process. People carrying out the administrative task in the past were not entirely aware of all internal regulations related to Permits/Injunctions. This may have been the root problem for several of the problems mentioned in this chapter.

3.6.6 Implementation of the system of filing and administering P/I requests is incomplete

While researching all regulations set up by the headquarters, it was found that the company did not entirely follow the required procedures. Relatively recently some changes had been made to the

process, that the company had not implemented yet. For instance there was a new template available that should have been used to file the reports, whereas the different departments still used a different, old, version of the template. Another example is that a certain type of report (Equipment Permit) had to be sent to the headquarters for review since recently, but this had not happened yet.

3.7 Demands stated by the company

While doing the research and before doing the internship interview, some requests and demands regarding the process were put forward by the responsible manager and involved specialists:

3.7.1 Demand for well defined tasks and responsibilities

One of the demands the manager put forward was that all tasks and responsibilities relevant to the process would be put in a single document, including a RASCI matrix with responsibilities. A concept of this document was already produced a year before, but it was incomplete and not in line with (current) regulations by the headquarters.

3.7.2 Demand for systematical monitoring of progress

The production department was the first department to ask for a way to systematically monitor progress of currently active cases. As such they were also my main sparring partner in the design of this tool.

3.7.3 Demand for measurable performance

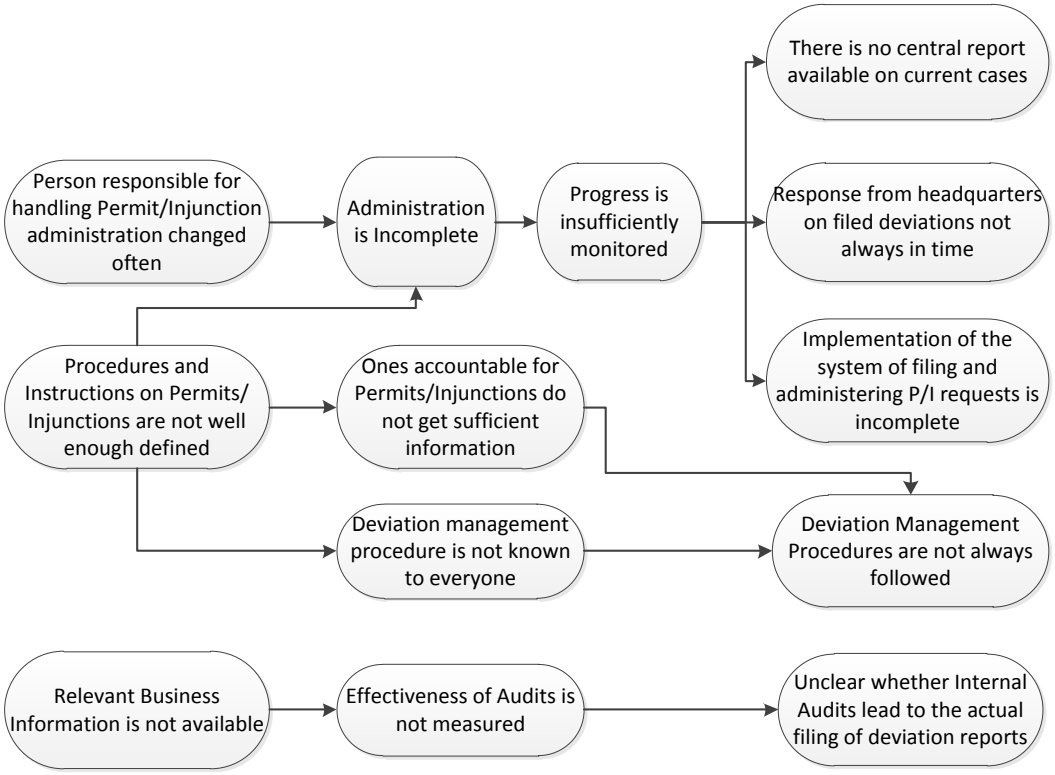
A request from both the Manager and the Packaging department was that the performance of departments and the influence on the performance per single case would be measureable. This required the to-be-implemented solution to correctly describe that compliance gap, requiring all cases to carry information on their impact on the department's compliance score, something not recorded in the past.

3.7.4 Demand for management information

The final request by the company was that management would get (better) management information, with a detailed view (where needed) per case, and an updated KPI to better reflect the process.

3.8 Root Causes

From all mentioned problems, a problem bundle is created to find the root causes that need to be solved in order to solve the problem The company faces. A problem bundle displays the relationships between problems and helps in finding root causes to the perceived problems.



Possible root causes can be found in the left part of the problem bundle, problems without a predecessor. The found root causes are:

- 'Relevant business information is not available'
- 'Procedures and instructions regarding Permits/Injunctions are not wel enough defined'

"Person responsible for handling Permit/Injunction administration changed often" is not considered a root cause as this is something out of control of either researcher or management, therefore it cannot be a solution to focus on this. One might say it's not even a problem, as problems are defined by Heerkens as deviations from expectation which can be resolved. This one can not. (Heerkens, 1997)

3.7 Conclusion

In short, the perceived problem of The company are:

- Implementation of the system of filing and administering Permit / Injunction requests is incomplete.
- There is no one clearly accountable for the process, administration is incomplete and progress is insufficiently monitored.
- There is no central report available on current cases.

- It is unclear whether Internal Audits lead to the actual filing of deviation reports, where necessary.

The root causes to this problem are that relevant business information is not available and procedures and instructions regarding Permits/Injunctions are not wel enough defined.

The following chapters describe how I solved the root causes to the problems and the resulting effects of the measures put in place.

4. Design of procedures and monitoring system and alternatives selection

The proposed route by the company to solve the root problem regarding procedures was to start with improving and finalizing a draft version of a document containing all responsibilities relevant to the process and implement it in the organization. The company uses a specific form of documents throughout the organization, containing a so-called RASCI matrix (defining who has Responsible / Accountable / Support / Consult / Inform roles to business processes).

This approach is in line with the Compliance Management life cycle proposed by Ramezani et al. Although in the case of the company it is not possible to work throught the entire cycle (see figure) due to the global organization being in control of the overall procedure. (Ramezani, 2012)

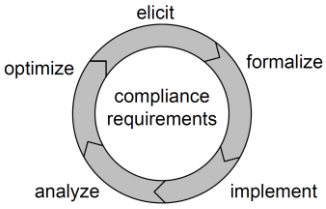


Figure 2: Compliance Management Life Cycle by Ramezani et al.

It does however imply that the process first has to be formalized before a Compliance Management system should be implemented. Due to the time restrictions of the internship it was decided that the process would partially work in parallel, however, starting point would be the draft version of the formalized Compliance (Deviation) management procedure.

Ramazani et al. further introduce the concept of separating business process management from compliance management. In short, a system running the business processes should be accompanied by a system monitoring its Compliance (Ramezani, 2012)

4.1 Modeling Workflows

In order to produce such a document, I first modeled workflows for the entire Deviation Management Procedure (DMP). As the global organization keeps its different plants very independent, workflows in this area can best be modeled as *inter organizational workflows.*

According to (Lawrence, 1997), inter organizational workflows can be defined into the following categories:

Category	Description
Capacity sharing	tasks are executed by external resources under the control of one workflow manager
Chained execution	the process is divided into subsequent phases and each business partner takes care of one phase
Subcontracting	a subprocess is executed by another organization
Case transfer	Each partner uses the same workflow process and cases are transferred from one partner to another.
Loosely coupled	each partner takes care of a specified part of the process

(Lawrence, 1997)

In the case of the DMP, 'Loosely coupled' fits well, with separate responsibilities for both parties. The company is expected to perform Audits, record deviations and suggest a solution to the deviation. The global organization must then subsequently give permission to the proposed route, after which the company can implement the agreed solution.

Van der Aalst gives guidelines for loosely coupled workflow processes using *asynchronous communication*, defining them as follows: "Loosely coupled workflow processes operate essentially independently, but have to synchronize at certain points to ensure the correct execution of the overall business process." (Aalst, 2000)

A basic property any interorganizational workflow should satisfy is soundess, individual workflows between the different organizations should be correct by themselves. This property was guarded while constructing the different workflows, both within the company as well as for the global organization. A list of all modeled workflows can be found in appendix D. These workflows were incorporated in a process manual, describing the tasks and responsibilities in detail. A simplified overview is displayed below. In order to follow the beforementioned compliance management design cycle, responsibilities were formalized in an official company document. On the following page, in chapter 4.2, the core of this document, a RASCI matrix (Responsibility/Accountibility/Support/Consult/Inform), is displayed.
[removed in public version]

4.2 Defining responsibilities

Based on the modeled workflows and process manual (not integrally encorporated in this document), the local procedure on Deviation Management was updated by the researcher. In the final week of internship the procedure was signed by the managers of the departments involved (Production, Packaging, Quality Assurance) and put in effect thereafter.
The critical part of the procedure, the RASCI matrix, is displayed below, showing the different responsibilities actors have. The workflows underlying this matrix can be found in appendix D.
[removed in public version]

4.3 Selection and Design of a system to monitor progress on filed deviations

As stated also by Silveira et al, not many software tools exist aiding in compliance governance. Based on information gathered from interviews throughout the company it was decided that clustering the data into one database and provide the information and tools asked for from that collected data would be the route to take to try and solve the 'business intelligence' problem the company faced. This way, relevant business information could be generated using the database and integrated into a dashboard. A similar approach is taken by Silveira et al. in a structured design of dashboards displaying Compliance information. (Silveira, 2010)

McKenna has run through a similar process in a lab-environment, using Excel and Access to implement a quality assurance system to file and categorize deviations and distill usefull information from it. (McKenna, 2003)

As the actual business processes behind the Permit / Injunction forms are quite specialistic and sometimes complex, it was decided that the implementation of the system would take place with regular input from the users. A participative design approach was taken, with a focus on delivering a prototype fast, enabling at least two rounds of testing and change/improvement before the internship period would end. In the meantime the selection of a final solution would take place. More on the selection of the type of design process can be found in chapter 1.3.

4.3.1 Formulation of possible implementation routes

Over the course of a few weeks, several solutions to the problem came forward. Of the following list, some I came up myself, some were suggested by my mentors and collegues from the quality department.

Excel + Word Mailmerge

With both applications readily available in business environments, combined with most white collar workers being able to work with both, makes this combination of tools seem to have one of the lowest access barriers.

Access

Using Access (compared to excel) would seem a logical choice, as the main needed functionality is to store/recall data using a form. Access however is not a standard available application within the company.

SAP QM
In parts of the organization, SAP is used to drive business processes. SAP also has a module for quality management. Implementation however is costly and time consuming.

Custom built PHP + SQL driven website
Accessible from anywhere (with an internet connection), can be made exactly to spec. Drawbacks are inflexibility after it is finished, security issues (no internal webserver available at the company, so must be hosted externally) and development time.

Smile
The company is using 'Smile', a software package used for both CRM and internal blockades for batches containing a deviation. As such a license is already purchased and many employees know how to work with the system. The workflow in the software seems suited to use for deviation management as well, but getting management information and reports to the headquarters out of it may be difficult and/or expensive to implement.

No Automatisation
Due to the relatively low number of cases (about 160 in three years) only improving procedures and responsibilities may just be enough to ensure a well functioning process and adequate information flow to the headquarters. Providing management information and workflow support would be inpractical though.

4.3.2 Selecting a solution

When selecting a (final) solution it is important that ranking criteria are selected, weighting established and solutions scored on the criteria. Based on conversations with the QA manager and various Specialists that will work with the system, I set up the following (non financial) criteria the alternatives can be ranked on:

Non-financial Criteria

Input Performance
This criterion measures all non-financial advantages of a good input performance (typing the reports into the system). The financial impact of faster input is taken into account in the financial measure.

Update Performance
This criterion measures all non-financial advantages of a good update performance (making (status) updates to reports). The financial impact of faster updates is taken into account in the financial measure.

Flexibility
The Deviation management procedure is still undergoing changes, the possibility the system will have to be adjusted (slightly) in the coming years is quite high. This criterion describes the amount of effort needed to change the system/procedures afterwards

Application Availability

This criterion displays how 'available' an application is. Can it run on any system within the company, or maybe even on a non-company computer, or is it limited on a single workstation (for instance due to licensing limitations).

Data Availability
How well is the data available for other uses then the ones described in this report? There is the hint with overlap with the 'flexibility' parameter, so it has to be pointed out this criterion only values the (ease of) export of data.

Data Security
How well is the system protected from data theft, is what this criterion measures.

Data Integrity (and backup)
This criterion finally is describing how safe the data is in the system, is the data salvageable if the system breaks down and how well/often is it backupped.

Financial Criteria
The advantage of financial criteria is that the monetary values can just be added up (after discounting) to create a TCO value for a given period. For this research a period of 5 years was chosen. The rationale behind the 5-year period is that technological improvements in the coming 5 years may bring new oppurtunities to implement a system like this one or make the old solution obsolete due to incompatibility with future software versions of –for example- Microsoft Office. Furthermore, the deviation management procedure itself is still evolving and may change in the future, requiring adaptations to / rewriting of the system. As it is currently unclear if and when the procedure may change and long term technological improvements fall outside the scope of this thesis, I will use a 5-year usage period in the TCO calculations.

The following financial criteria were defined:
Licensing costs
The costs associated with buying or renting a license (per year).

Customization costs
The costs associated with customizing the software, if needed.

Training costs
The costs of Training (trainers + time lost for trainees) to enable all actors to work with the system as supposed.

Operational costs
All costs to be made to operate the system on a yearly basis, mostly man hours to do all entry/export/reporting work. A detailed calculation/estimation on this can be found in appendix C.

4.3.3 Weighting and scoring of criteria
The weighting of the criteria is based on the opinions of the QA manager, my mentor and my own, based on interviews with other people. The non financial score was put together by weighting the

attributes using SMART and valueing them based on interviews with specialists from the company. Financial score was calculated by estimating Licensing, Training, Customization and Operational costs over 5 years using DCF (Discounted Costing) and discount them for the estimated The global organization reinvestment rate. The following tables display the results of the DCF and MCA, of which details can be found in appendix C.

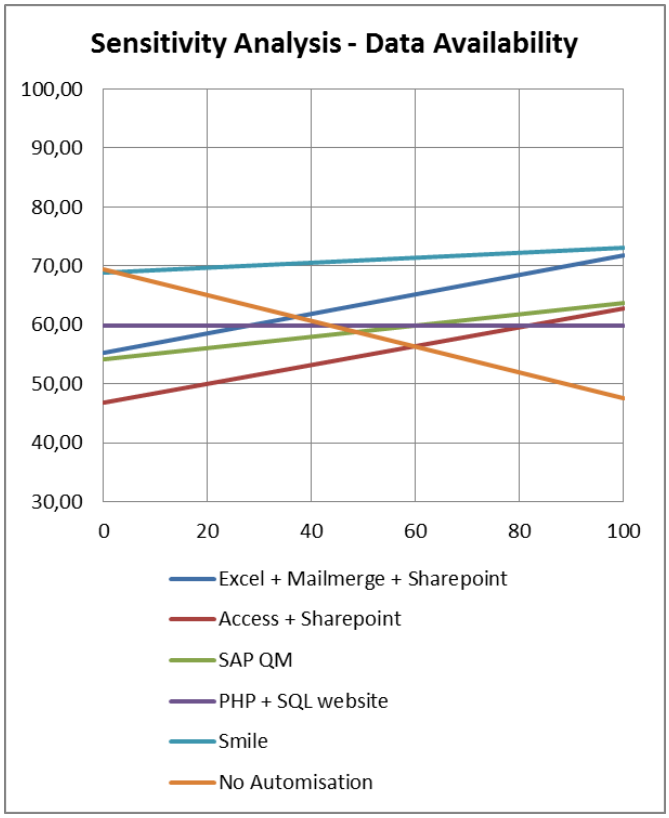
[removed from public version of the report]

Figure 1: DCF

[removed from public version of the report]

Figure 2: weights and scores

After being initialized, the set weights were evaluated using sensitivity analysis. Below is a graphical representation visible of the most influencial criterion, Data Availability (See appendix C for the other criteria):



As can be seen, the 'Smile' alternatives scores consistently well, independent from the weight of the 'Data Availability' criterion. The 'Excel' alternative does rely heavy on this criterion.

With the weights and criterion scores set, the total score on financial and non financial parameters totals up to:

[removed from public version of the report]

Figure 3: Sensitivity Analysis Data Availability

Drawing all alternatives in a graph, with the non-financial scores on the x-axis and the financial scores on the y axis, allows to draw an 'efficient frontier' between the 'smile' and 'excel' alternatives.

[removed from public version of the report]

Figure 4: total scores

4.3.4 Conclusion

Based on these findings it was decided that the prototype built in Excel (See chapter 5) parallel to the final selection process would be finalized and used in production. If time permitted the possibility would be researched to use an SQL database for storing data instead of Excel. The company already has an SQL server; using it also for this purpose would not lead to extra costs.

5. Evaluation of development process

In this chapter the development process of the designed system is described. From the first prototype in excel to the monthly development cycle and the final additions made in the last month of the internship.

5.1 Design of the First prototype: Excel + Mailmerge

Due to the limited time available compared to the time needed to fully integrate a new system into the organisation, it was decided that a prototype of a system would be built first, while in parallel the final selection of a system would take place. This way the different actors could already get used to a more systematic approach to the deviation management procedure, where feedback on the prototype could be used as input for implementation of the final solution.

Restrictions on software that could be run within the company lead to the decision that the prototype would be made in Excel (augmented with some VBA macro's were needed), with the 'Mailmerge' function of Word as the tool interfacing with the excel 'database' to create the output (progress/actual reports). (Alternative 1 from chapter 4). Ease of implementation and flexibility are also advantages of this method of prototyping. This paragraph describes the implementation of this prototype, the selection of the final system is described in paragraph 4.3.

After first creating a tool to edit / save / search within the database using Macro's, first I made sure the digital database was up to date. After a few days of collecting data and searching through paper archives, I had a list of 148 filed reports, with all relevant information stored in the database, so the reports could be reproduced from it (except the signature of course).

[removed from public version]

Figure 3: Example of a report entered via the input-tool

[removed from public version]

Figure 4: Operations available on the input-form

After creating this input-tool, the second step was to enable reports to be printed out again (based on the information stored in the database), so I could present the current cases to their (original) owners, to check the progress on them. My first attempt by using Excel to fill in the data in a special workbook was not succesfull, as I got complains that the layout was not exactly as the original documents (due to limitations in Excel with data handling in merged cells). I used a Mailmerge to dynamically fill word documents instead, where such limitations are much less an issue.

[removed from public version]

Figure 5: example of an export using mailmerge

Within Mailmerge it is possible to set filters and sort the data as preferred, enabling to filter on (in this case) original author, so I could print the active cases per specialist and gather status information from any of them.

[removed from public version]

Figure 6: Example of filter setting

Using the mailmerge I was able to classify all cases. In order to systematically doing so, I first studied the documentation from the global organization, stating procedures and deadlines per type of form. I translated this information into ten phases a case could be in, and defined deadlines for every phase, different for Permits and Injunctions.

The headquarters also uses a status indication, however it is less detailed. In the top right of the image below the equivalent headquarterse status was matched with the newly defined phases

[removed from public version]

Figure 7: Phases and deadlines per document type

With the phases defined I set out to get the 'phase' correct for every document in the database. I used data available, but for some cases I had to speak the original author to get the information correct. With the phases for all documents up to date, it was time to work on a (monthly) report for specialists, enabling them to keep a grip on the progress of current cases and be reminded if a deadline would approach.

Also in figure 9 (previous page) is displayed the deadlines that were set for every step, and the to-be-taken action at every phase. Using this information and again a custom mailmerge, I created an output file that could be sent to the specialists every month by mail. After a few testing rounds some improvements to the original design were made, for example the addition of the compliance impact and the coloring of the deadline counter based on the amount of time left.

[removed from public version]

Figure 8: example of (part of) a monthly update

5.2 Iterations during the development process

During the process of development a prototype was delivered quickly, after which in a monthly cycle a new iteration was delivered; improvements were made for the next cycle (month). This way the contact with users was frequent enough to reflect on suggested improvements, but it was prevented that the user input took too much time (for both user as well as the developer). Every month an evalutation was written on which improvements were implemented.

5.2.1 First Iteration

During the first month the reports went live, I specifically asked actors for input on the forms and reports. From most users no feedback was received however. This seems to be the culture within the company. The feedback I did get was largely positive; it was perceived that the monthly update with the status on all current cases (per actor) gives a clear overview where one stands and where the process needs attention.

These other issues were found and resolved after the March evaluation:

- Days left before deadline calculation not working correctly
- Missing function: export to the global organization formatting of entire file. Made export tool.
- Set up ID system caused issues with higher hand changed form types. Changed to compensate.
- Difficult for inexperienced personnel to fill in files. Added checks on the input with error reporting using colours

5.2.2 Second Iteration

During the second iteration, the export functionality turned out very useful when an external audit was performed at the plant. It did prove however that documentation still needed some improvement as I had to assist in generating the needed documents. The specialist involved did however understand the possibilities of the system and was eager to make use of it.

These other issues were found and resolved after the first iterations' evaluation:

- Difficult to track changes made in digital file. Solution: Lock out textual changes after step 4 (sign off of document); added a transaction log to the file
- Missing Function: Dashboard. Implemented (draft)
- Write/Expand documentation

5.2.3 Third Iteration

During the third iteration, the input side of the system received some testing with the Laboratory producing a large number of injunction requests with the newly made input sheet with checks on inputted values. 18 files were produced without any input needed from my side; with all necessary info present.

These other issues were found and resolved after the third iterations' evaluation:

- There will be no monthly update mail for managers (as proposed earlier). Instead, a quarterly report will be produced which the managers will use to stay in control of the process.
- Dashboard was developed with a customizable waterfall graph for impact of investments in compliance score. In order to let it give reliable results an accurate impact of all current permits/injunctions on the compliance score is needed.

5.2.4 Final evaluation

During my last weeks of the internship period I made some final changes to the project. After this I will remain with the company for at least 6 months, for one day a week maintaining the system and assist the Packaging department in producing permit/injunction requests. During this period a SQL database was setup to investigate the possibility to separate the data from the input form. With the limited set of tools available at the company it turned out however that using SQL for this system would not give practical benefits, as updating date on the server required a tool only available for some employees. During the last weeks of the period it was found that the Engineering department would be implementing the deviation management procedure (including permits/injunction) soon. The final weeks were also used for the following:

- Teaching administrative process to a second person as fallback
- Preparing the system for use with Engineering Permits/Injunctions
- Finalizing quarterly report
- Completing the database with compliance impact from historical (already active) cases.

5.3 Additional functionality: Adjusted compliance KPI & Dashboard

With the data available in the system, during the final month I was able to implement some features that were not necessarily intended beforehand. This paragraph describes two of them.

Currently, the only performance indicator related to the deviation management procedure is the 'compliance' figure, for each of the three related departments (production, packaging, quality control). This KPI however does not take into account efforts in the procedure itself. Therefore, I prepared a proposal for the the company management to come to an 'adjusted compliance' that does exactly this. The full text of the proposal can be found in appendix E. The gist of it however is that departments are expected to describe the compliance gap with Permit/Injunction forms and prevent the files from going overdue. This is the kpi buildup:

[Adjusted Compliance]=[Compliance]+[Described Compliance Gap]*50%–[Undescribed Compliance Gap]*50%

Definition of Compliance: Compliance is the known compliance score.
Definition of Described Compliance Gap: The amount of compliance gained when all currently active, signed, not overdue permits and injunctions are closed and signed off.
Definition of Undescribed Compliance Gap: The amount of compliance missing, but not yet described in a permit/injunction.

For managers, the kpi is made visible in a dashboard, also containing, next tot the kpi itself, the parameters that make it up, so it is quickly visible how the score is built up and where possible problems may lie. On the following page is a draft of the dashboard visible. The data in it are partly randomly generated as at the time of writing the report, all compliance impact for the different already active cases was not known yet. Using the selection box in the left top, it is possible to select a (fiscal) year to evaluate and change the displayed departments (this screenshot shows all departments)

[removed in public version]

5.4 Improvements of impact representation

By request of the operational director of the company, I developed a customizable waterfall graph, visualizing the impact of investments and procedural improvements. With the help of this tool it is possible to project compliance improvements over time. The graph is generated dynamically based on the input in the system and the variables set by the user. A screenshot can be found below: [removed from public version]

With the configuration options (left) it is possible to set the following parameters:

Min Phase	What is the minimal progress made so far to allow cases to be represented in this graph
Max Phase	What is the limit on progress made so far to allow cases to be represented in this graph
Standard	Selection of Production / Packaging / Microbiology Standard
Fiscal Year	What fiscal year must be represented

This way, with a single graph, a multitude of views can be created of the process. As the Phase describes the entire workflow of handling a deviation, it is easy to omit (for example) cases that have not got official permission to resolve from headquarters, specifically select cases that are still in the phases of receiving permission or only select ones that have already been implemented. For a detailed overview of all phases see '*Modelled workflow phases and deadlines per type of deviation*' *in appendix D.*
For each Quarter (in which CAPEX is divided over the year), the two cases with the largest impact on compliance are mentioned seperatedly, possible other cases are summed in a third block, mentioning the amount of cases in it and the total impact they have combined. This way the graph has a fixed layout, independent from the amount of solved cases per quarter.

5.5 Implentation conclusions

When comparing the 'before' and 'after' status of the DMP implementation within the company, the changes are very noticeable. The system designed as described in the rest of this chapter lead to a situation where now the status and required followup (including deadline) of every case is known, with all information available in a structured manner in the form of monthly updates to all actors.

The extra designed features described in 5.4 allow the company to better track its improvement progress. The completion of the mapping of the entire compliance space (as further elaborated on in appendix D) is taken up as one of the mid term strategic goals for the company. The developed tool continues to be in use after the internship period and now acts as the main backbone for the administrative process behind the DMP.

6. Conclusions and Recommendations

In this chapter the final conclusions are put forward, accompanied by recommendations for the future direction of the DMP within the company.
The central research question of this thesis was: *How can the compliance management process within the 'Operational Company' of the company be structured?* After completing the described research, the following conclusions can be drawn and recommendations be given:

6.1 Conclusions

This thesis shows that the company had issues with its implementation of the Deviation Management Procedure from the global organization. Translating it into a local procedure forced involved managers to focus on the requirements put forward by it, help greatly to reduce discompliance to the compliance management procedure itself.

The performed modelling of the workflows into flowcharts and translating the global procedure in the local language and template enabled me to put any current (and new) cases in a 10-phase classification, finally giving an systematic overview of the Production, Packaging and Laboratory performance on execution of the procedure.

The newly acquired business information is now used for a periodic update of actors tasked with resolving devations. Compared to the 'before' situation, all actors are now aware of approaching deadlines. Managers now have the tools to keep track of improvements made to the affected business processes.

The selection of the 'Excel + mailmerge' implementation turned out to be a good one, as adjustments due to the introduction of Engineering Standards was easily implemented. If a less flexible solution was chosen, those adjustments might already turn out to be costly.

This, or a similar tool, may also be implemented in other plants within the global organization, as it greatly improved information and grasp on the process. If the global organization would decide to roll out such a system globally, the multi criteria analysis would have to be done over, as in a globall roll out scores on criteria for the different alternatives may turn out quite different in that case.

Looking back, the problems found in the early phases of this research (see 4.1) have been resolved; the developed system is now in production and the document containing the improved procedures has been signed by the management team and will be in effect soon.

6.2 Recommendations

The functionality provided with the developed toolset, combined with the remodelled workflow embedded in the related procedure allows the company to more effectively keep track of progressions made in the DMP.

As the DMP is a procedure used worldwide by the global organization, other plants might benefit as well. It would be highly recommended to further research this opportunity to implement the automisation of and workflow management within this process. If one would venture in this direction, it would be recommended to do further research into the platform to be used when implementing the system. If it would be used globally, a solution more based on the net comes to mind.

It would not be surprising if a selection procedure for a global rollout would lead to a webbased choice. The extra investments needed for implementation would most probably be offset by reduced cost of maintenance, as only one such system would be needed for all plants. The global organization already has quite some experience with webbased tools for inter-plant comparison tools, online collaboration, monthly plant reports et cetera. A new system for handling compliance management could possibly be a good addition to the available global systems. It would be wise however to first let the entire Deviation Management Procedure crystallize out, before such a system should be implemented.

7. Bibliography

Aalst, W. v. (2000). Loosely coupled interorganizational workflows: modeling and analyzing workflows crossing organizational boundaries. *Information & Management 37*, 67-75.

Ackoff, R. (1967). Management Misinformation Systems. *Management Science*, 147-156.

Anderson, E. (1985). Managerial considerations in participative design of MIS/DSS. *Information & Management*, 201-207.

Belton, V. (1986). A comparison of the analytic hierarchy process and a simple multi-attribute value function. *European Journal of Operational Research 26.1*, 7-21.

Boltic, Z. R. (2010). Measuring the performance of quality assurance processes: pharmaceutical industry deviation management case study. *Accreditation and Quality Assurance* , 629-636.

Dickson, G. S. (1984). The Behavioral Side of MIS. *Business Horizons*, 137-155.

Hasvold, P. &. (2011). Flexibility in interaction: Sociotechnical design of an operating room scheduler. *International Journal of Medical Informatics 80.9*, 631-645.

Heerkens, H. (1997). *The Managerial Problem Solving Method." .* Enschede: TSM Business School.

Karlsson, F. H. (2012). Exploring user participation approaches in public e-service development. *Information Quarterly, 29(2)*, 158-168.

Lawrence, P. (1997). *Workflow Handbook.* New York: Workflow Management Coalition, Wiley.

McKenna, J. D. (2003). Development and operation of a quality assurance system for deviations from standard operating procedures in a clinical cell therapy laboratory. *Cytotherapy*, 314-322.

Mehmet Pasaogullari, P. W. (2013, 01 09). *Clevelandfed.org*. Retrieved 04 22, 2013, from Survey Measures of Inflation Expectations: http://www.clevelandfed.org/research/trends/2013/0113/01infpri.cfm

Olson, M. I. (1981). User involvement in system design: An empirical test of alternative approaches . *Information & Management*, 183-195.

Ramezani, E. F. (2012). Separating compliance management and business process management. In E. F. Ramezani, *Business Process Management Workshops* (pp. 459-464). Berlin Heidelberg: Springer.

Silveira, P. R. (2010). On the Design of Compliance Governance Dashboards. In P. R. Silveira, *Service-Oriented Computing.* (pp. 208-217). Berlin Heidelberg: Springer.

Verschuren, P. D. (2003). *Het ontwerpen van een onderzoek.* Utrecht: Lemma.

Yip, F. W. (2007). Rules and ontology in compliance management. *Enterprise Distributed Object Computing Conference* (pp. 435-435). IEEE.

[Various references used in removed parts of this public version of this report have been removed from this list]

8. Appendix

a. Answers to Research & Managerial design Questions

Research questions

This information is in another form also covered in the main text. This list is presented for a quick overview of answers to the research questions.
[removed from the public version]

Managerial Questions for participative design (Anderson)

1. **Does the user(s) have enough knowledge and experience in the technology or its application to meaningfully contribute to system development?**
   Amongst the users of the system, there is a great difference in experience with and 'feeling' for the technology used. All users however are able to work effectively with the systems and give feedback on possible improvements.

2. **How structured are the applications of the system and to what extent do these applications involve numerous exceptions?**
   Inherently the system needs some flexibility as the DMP isn't set in stone entirely yet. Using high level applications this flexibility can be assured.

3. **How much job, interpersonal, and organizational change is introduced by the system?**
   The actual change to all three is limited. The procedure itself is already in place, the system will take care of the administrative part of the process, as well as monitoring the workflow.

4. **Is the project leader commited to and skilled in the application of employee participation, and does user involvement have the support and endorsement of management?**
   In this case where the project leader is the same person as the one initiating the project, giving a objective answer to this question is difficult. It is clear however that there is endorsement by management and at least part of the users is involved with the system.

5. **Does the user possess or are you willing to grant him/her substantial influence to determine directions and solve user-analyst conflicts?**
   Substantial user input is exactly what is preferred, as they are the ones who'll have to work with the system day by day.

6. **Are you willing to accept the time delays associated with a constructive level of user involvement?**
   In the time planning there is ample time reserved for revisions based on user input.

7. **Does the user(s) want to be involved?**
   Most users turn out to be quite involved with the process, keen to see it improved.

b. Decision on what system to use (MCA)

MCA was performed using SMART (Simple Multi Attribute Rating Technique).
The final score was as follows:
[table removed from public version of report]

Non financial score was calculated in the following way: Weight times score on the different criteria, divided by the sum of all weights. Weights of criteria were set by averaging the weights given by 3 people (manager, QA specialist and myself) and then evaluated using sensitivity analysis (see two pages ahead).

The actual scores on the different criteria by the alternatives were set by me, based on interviews with 2 QA specialists (one of which is internal owner of the current Smile implementation within the company, my own input and information from the the company IT department.

[table removed from public version of report]

TCO was calculated based on the following figures:
[table removed from public version of report]

The operational costs were calculated in the following way, using estimations of the amount of time different tasks would cost on the different alternatives, multiplied by the frequency of the tasks:
[table removed from public version of report]

Discounting was done in the following way:
[table removed from public version of report]

Rationale for the 7% re-investment rate is the high organic growth and projections do to so in the future by The global organization, making it easy to reinvest any money spent for a good rate somewhere else in the company. 2,5% inflation is based on the 5-year SPF CPI developments (Philadelphia Fed's Survey of Professional Forecasters , Consumer Price Index). This is not covered more deeply here as it falls outside the scope of the research. (Mehmet Pasaogullari, 2013)

The inflation number was used to index the yearly costs of licensing and operational costs. Training and customization costs were taken in T0. The 7% re-investment rate was finally used to calculate the discounted cashflow on T0 using also the data T1-T4.

In selecting the alternative, a graphical representation was chosen, with on the x axis the non financial score, and the financial score on the y axis. A efficient frontier could then be drawn: [table removed from public version of report]

Sensitivity analysis of the weights of the criteria:

[tables removed from public version of report]

c. Modelled workflows

[removed from public version of report]

Actor: Administration

Actor: Specialist, Permit

Actor: Specialist, Injunction II

Actor: Specialist, Injunction I

Actor: TD

Actor: Hub

Modelled workflow phases and deadlines per type of deviation

d. Adjusted Compliance KPI proposal

This is the proposal as made to the company Management.

[removed from public version of report]

f. Side Project: company Global KPI representation

[removed from public version of report]

g. Side Project: Production Dashboard

[removed from public version of report]

h. Selection of academic literature

When searching for scientific literature, both Scopus and Google Scholar were used. Below there are abstracts displayed (where available in English) of the literature referenced to in this thesis. Per search query the standard listing of both search engines was used, unless stated otherwise. Articles were selected firstly by title; then by abstract. As using the standard selection of the search engines mostly lead to articles with some age, but a high number of references; a custom query was performed at Scopus to obtain more up-to-date articles to validate the current use of (in that particular case) participative design approach. From all queries the first three pages were studied. Some articles were obtained by a top-down search from the article "Managerial considerations in participative design of MIS/DSS" as a methodology from that article has been used in the research. The search was initially focused on articles relating to "Deviation Management", however this definition turned out to be mostly used in studies relating to laboratories and other clinical institutions. "Compliance Management" is the broader term used in relation to the process the research focused on

Using Scopus: "modelling business workflow in IT"

Loosely coupled interorganizational workflows: Modeling and analyzing workflows crossing organizational boundaries

Today's corporations often must operate across organizational boundaries. Phenomena such as electronic commerce, extended enterprises, and the Internet stimulate cooperation between organizations. Therefore, it is interesting to consider workflows distributed over a number of organizations. Interorganizational workflow offers companies the opportunity to reshape business processes beyond the boundaries of their own organizations. Two important questions are addressed in this paper: (1) what are the minimal requirements any interorganizational workflow should satisfy? and (2) how does one decide whether an interorganizational workflow, modeled in terms of Petri nets, is consistent with an interaction structure specified through a message sequence chart?

Google Scholar: "participative design information", retrieval via Scopus

Managerial considerations in participative design of MIS/DSS

There is widespread support for the concept of participation in systems design and development, but inconsistent evidence as to its contribution to systems success. These results are entirely consistent with those of the behavioral sciences where participation has been studied under many different conditions. Managers of design processes need to adopt a more complex view of participation and evaluate its probable contributions and limitations in particular applications. Drawing upon research results from within and outside the field of information sciences, decision guidelines for managing the extent and character of participation have been proposed. These guidelines stress that consideration be given to various contextual aspects of the problem, technology, user(s), job tasks, and organizational design.

(used in article Managerial considerations in participative design of MIS/DSS)

Management Misinformation Systems

Five assumptions commonly made by designers of management information systems are identified. It is argued that these are not justified in many (if not most) cases and hence lead to major deficiencies in the resulting systems. These assumptions are: (1) the critical deficiency under which most managers operate is the lack of relevant information, (2) the manager needs the information he wants, (3) if a manager has the information he needs his decision milking will improve, (4) better

communication between managers improves organizational performance, and (5) a manager does not have to understand how his information system works, only how to use it. To overcome these assumptions and the deficiencies which result from them, a management information system should be imbedded in a management control system. A procedure for designing such a system is proposed and an example is given of the type of control system which it produces.

The behavioral side of MIS Some aspects of the "people problem

To enjoy the technical benefits of management information systems, it is often necessary to solve the dysfunctional side effects stemming from behavioral problems—in short, people problems. Reactions to the installation of MIS may range from failure to use the output to outright sabotage. The authors identify three types of dysfunctional behavior—aggression, projection, and avoidance—that may appear in four groups—operating personnel, operating management, technical staff, and top management. Only the technical staff—being designers and agents of change—shows no dysfunctional behavior. Operating management, the group that should enjoy most of the system benefits, goes farther than any other group in its resistance, and exhibits all three forms. The authors suggest ways of minimizing the behavioral problems that may follow introduction of MIS

User involvement in system design: An empirical test of alternative approaches

User involvement in the development of information systems is often assumed to be key to successful implementation. However, few empirical studies have clearly demonstrated a relationship between user involvement and two key indicators of system success: system usage and user information satisfaction. The authors test the general hypothesis that user involvement is a more complex concept than previous research would indicate; there are different types of involvement and different stages in the system development life cycle in which users may become involved. In a study of 83 users in 23 companies, they found that only the activity of user sign-offs on project phases had a significant correlation with both user information satisfaction and satisfaction with the information systems group. The authors conclude that there is a complex relationship between the type and degree of user involvement and other organizational and individual factors; this relationship affects both user satisfaction with and usage of the resulting systems. Some suggestions for further research taking this complexity into account are given.

Scopus: ALL("participatory design" information) AND LIMIT-TO(pubyr, "2013,2012,2011,2010,2009")

Flexibility in interaction: Sociotechnical design of an operating room scheduler

Purpose:The purpose of this study was to learn about factors that influence the design and implementation of situated computing solutions that support hospital work. This includes social and technical aspects of the actual systems that will be implemented, as well as the appropriate design methodology for developing these systems.

Methods:Staff at a surgical department at a University hospital were engaged in a participatory design (PD) process to help solve a problem that was presented by the staff: scheduling of patients and surgery rooms, and creating awareness of the status of ongoing surgeries. The PD process was conceptually aided by a model that describes Medical Informatics Systems as comprising of three components, a service component, a technical component and a social component. The process included the use of ethnographic field work and iterative redesign of both technical and social components of the system after it had been implemented into day-to-day work practice.

Results:The PD process resulted in the creation of a system that was iteratively created over a period of about 2 years, and which then handed over to the IT department of the hospital and used by the surgical department for a period of about 1 additional year. The first version of the prototype that was implemented contained usability flaws that made the system difficult to use in time critical situations. As a result of observations and a redesign of the technical component and social component of the system a new version was possible to implement that managed to overcome this problem. A key feature of this second version of the system was that some responsibility for data entry validation was shifted from the technical component of the system to the social component of

the system. This was done by allowing users to input poor data initially, while requiring them to fix this data later on. This solution breaks from “traditional” usability design but proved to be quite successful in this case. A challenge with the solution, however, was that the IT department could not understand the concept of systems being described as comprising of both social components and technical components, and thus they had difficulty in understanding the overall design of the system during the handover process.
Conclusions:Situated computing can present a number of design challenges that may not be easy for designers and hospital workers to understand before a system has been implemented. Situated computing development may thus need to be aided by PD that includes both ethnographic observations and iterative redesign of the system after it has been implemented. Traditional data validation mechanisms may create poor system performance in cases where users are rushed to input data into the computer due to pressures created by other more critical work activities. In this case it may be better to rely on social mechanisms for correcting errors later on, rather than error catching mechanisms that reject incorrect data. It can be challenging, however, to maintain such systems over time, as IT-departments may lack skills and interest in social components.
Exploring user participation approaches in public e-service development
It has been argued that user participation is important when public authorities develop e-services. At the same time there is limited research on the usefulness of existing user participation approaches in public e-service development. In this paper we, therefore, analyze how the three user participation approaches – participatory design, user-centered design, and user innovation – meet the strategic e-service goals of the EU and the US. In doing so, we identify three challenges that need to be considered when choosing among these approaches: 1) unclear user target segments can impede the fulfillment of usability and relevance goals, 2) the nature of participation can impede the fulfillment of democracy goals, and 3) lack of adequate skills can impede the fulfillment of efficiency goals.

Google Scholar: “simple multi attribute rating technique”
A comparison of the analytic hierarchy process and a simple multi-attribute value function
The paper reviews the applicability of approaches to multiple criteria decision making to aiding in the selection of a preferred option from a short-list of alternatives in the light of a wealth of information about those alternatives. It is concluded that Saaty's Analytic Hierarchy Process and a Simple Multi-Attributed Value Function are the approaches best suited to this problem and the most widely used in practice. The paper goes on to compare these approaches in detail from both a theoretical and a practical standpoint. The underlying assumptions of each are examined and considered in the light of practical decision aiding. The practical implications of the use of each approach are discussed. Reference is made to experimental work carried out by the author which has examined both practical and theoretical aspects of the use of each approach in isolation and in comparative studies. The paper will be of relevance to anyone facing a decision involving a finite number of alternatives and multiple criteria and considering the use of a formal approach.

Scopus: “Deviation Management”
Measuring the performance of quality assurance processes: pharmaceutical industry deviation management case study

This article presents experience from the practice of a successful pharmaceutical company related to design and implementation of performance measures (PMs) for deviation management linked to the analysis of impact on the production cost for the selected product. Case study focuses on PMs within good manufacturing practice (GMP) processes related to quality assurance (QA) and quality management, with the aim of complying with its future requirements proposed by the European Commission. Critical areas were identified based on data gathered from the industrial deviation database. Implementation of the suggested corrective actions showed significant improvement in

terms of reducing their number for more than 50% per selected deviation category. The results obtained in the course of this practice-oriented study contribute to further improvement of deviation management in the pharmaceutical industry and performance measurement of other GMP processes. The suggested performance measurement concept and problem-solving techniques may serve both practitioners and the decisionmakers within QA and quality control (QC) in order to improve their processes by implementing relevant regulatory requirements for quality management and maintain compliance.

Development and operation of a quality assurance system for deviations from standard operating procedures in a clinical cell therapy laboratory

Background

Errors and accidents, or deviations from standard operating procedures, other policy, or regulations must be documented and reviewed, with corrective actions taken to assure quality peiformance in a cellular therapy laboratory. Though expectations and guidance for deviation management exist, a description of the framework for the development of such a program is lacking in the literature. Here we describe our deviation management program, which uses a Microsoft Access database and Microsoft Excel to analyze deviations and notable events, facilitating quality assurance (@) functions and ongoing process improvement.

Methods

Data is stored in a Microsoft Access database with an assignment to one of six deviation type categories. Deviation events are evaluated for potential impact on patient and product, and impact scores for each are determined using a 0-4 grading scale. An immediate investigation occurs, and corrective actions are taken to prevent future similar events from taking place. Additionally, deviation data is collectively analyzed on a quarterly basis using Microsoft Excel, to identify recurring events or developing trends.

Results

Between January I, 2001 and December 31,2001 over 2500 products were processed at our laboratory. During this time period, 335 deviations and notable events occurred, affecting 385 products and/ or patients. Deviations within the 'technical error'· category were most common (37%). Thirteen percent of deviations had a patient and/ or a product impact score ~ 2, a score indicating, at a minimum, potentially affected patient outcome or moderate effect upon product quality.

Discussion

Real-time analysis and quarterly review of deviations using our deviation management program allows for identification and correction of deviations. Monitoring of deviation trends allows for process improvement and overall successful functioning of the @ program in the cell therapy laboratory. Our deviation management program could serve as a model for other laboratories in need of such a program.

Google scholar: "Compliance Management Audit"

On the Design of Compliance Governance Dashboards for Effective Compliance and Audit Management

Assessing whether a company's business practices conform to laws and regulations and follow standards, i.e., compliance governance, is a complex and costly task. Few software tools aiding compliance governance exist; however, they typically do not address the needs of who is in charge of assessing and controlling compliance, that is, compliance experts and auditors. We advocate the use of compliance governance dashboards, whose design and implementation is however challenging for these reasons: (i) it is fundamental to identify the right level of abstraction for the information to be shown; (ii) it is not trivial to visualize distinct analysis perspectives; and (iii) it is difficult to manage the large amount of involved concepts, instruments, and data. This paper shows how to address these issues, which concepts and models underlie the

roblem, and, how IT can effectively support compliance analysis in SOAs.

*Google scholar: "*Design of Compliance Management"

Separating Compliance Management and Business Process Management

The ever growing set of regulations and laws organizations have to comply to, introduces many new challenges. Current approaches that check for compliance by implementing controls in an existing information system (IS) decrease the maintainability of both the set of compliance rules and the IS. In this position paper, we advocate the separation of the compliance process from the organization's business processes. We introduce a life cycle for the management of compliance rules. A separate compliance engine is used to define and check compliance rules independent from the existing IS within an organization.

Rules and Ontology in Compliance Management

Compliance Management (CM) is the management process that an organization implements to ensureorganizational compliance with relevant requirement sand expectations. It is a continual, manual and laborintensive process that is proved to be of great challenge for many organizations. CM affects almostevery aspect of an organization and is in nature acomplex problem due to voluminous knowledge and data involved. In our attempts to automate and simplifycompliance, we propose and examine a semantic rulebased approach for modeling compliance knowledgewith the use of semantic web rules (SWRL) and webontology language (OWL). We study the use of exception handling approach to create a more robustrule base to deal with data incompleteness in the semantic web.

i. Interview plan (in Dutch)

[removed from public version of report]

j. Time Planning Internship (in Dutch)

[removed from public version of report]