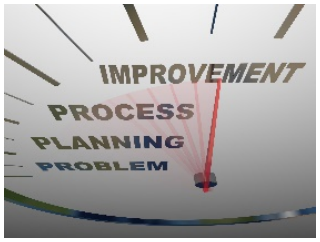
Leveraging automated asset management in the pharmaceutical industry



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MACS
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Contents

1. Introduction

The Life Science Industry always has been a stringently regulated industry. A pharmaceutical company has to comply with a wide range of regulations, rules and directives such as 21CFR[1] and EU-GCP[2], and equally be GMP[3] and GDP[4] compliant. Also, continuous developments both within and outside of the industry the recent years have made the life science industry ever more demanding and competitive.

As a consequence, pharmaceuticals will be facing increasingly more challenges in the coming years. Pharmaceuticals could positively and actively turn these challenges into opportunities by leveraging IBM's Maximo asset management software.

Based upon the deployment of IBM Maximo Asset Management at several well-known pharmaceuticals, one of Europe's leading asset management software deployment firms, MACS, has put to use its experience in deploying Maximo at several prominent pharmaceutical companies to prove that IBM Maximo offers numerous advantages as a centralised automated asset management system. Intelligent and easy-to-use modules such as Maximo Calibration, Maximo Scheduler and Maximo Mobile have attributed to the substantial success of the deployment.

This paper discusses the current and up-coming trends in life science and how a centralised IBM Maximo Asset Management System can support in facing these challenges and in gaining a competitive edge.

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[1] 21CFR refers to Title 21 Of Code of Federal Regulations

[2] EU-GCP stands for European Good Clinical Practice

[3] GMP is the abbreviation for Good Manufacturing Practice

[4] GDP stands for the Good Distribution Practice

2. Four challenges the pharmaceuticals will face

Both the pharmaceutical industry itself as well as general media all around report intensively about on-going developments within the pharmaceutical environment. Although the industry faces numerous challenges as described by PWC (2012), this paper will focus on four specific yet significant highlights.

2.1 Medicine selection control process

Payers and clients have become increasingly in control of what medicines are used and prescribed. Reforms are taking place in the provision of medicines. The influence of the payer, customer and – in particular - insurance companies on which brands and medicines will be selected for use is on the rise. Consequently, pharmaceuticals must improve their delivery to be on the short-list. Centralised automated maintenance management software will support efforts to enhance delivery by reducing cost at the different stages of the production cycle and even post production. It will enable the company to invest more in quality and performance.

2.2 From treatment to prevention

The focus in healthcare has slowly shifted from treatment to prevention. The overall shift in the vision of healthcare providers has not gone unnoticed in the industry. PWC (2012) stated that early diagnosis and prevention were the top goals of the Healthcare providers in 2012. More focus on prevention results in the adaptation of the healthcare approach of pharmaceuticals. Here, centralised and automated asset management supports in this trend by providing flexibility, gaining insights, supporting decision making and amending production where required.

2.3 Demand rise in emerging markets

There is an on-going market shift in which emerging markets realise a higher demand for medicines than in the traditional, industrialised markets. A growth of 165billion will be realised in 2016 according to FiercePharma (2013). The pharmaceuticals that prepare themselves with a central maintenance management system will have the ability to adapt to changes in purchase and inventory requirements much more quickly. Furthermore, expanding to new markets will mean new or expanding regulations. Working with one central IBM Maximo Asset Management for different locations means that the expansion and delivery to new markets can be supported more easily.

2.4 Intensified competition due to patent expiry

Patent protection has been running out the last few years during the so called patent cliff. For some companies major patents will be running out the coming years. The patents expiration has resulted in a more competitive market that needs to produce even more cost effective and efficient than ever before. Using a centralised IBM Maximo application in its full capacity will ensure that companies are fully prepared for a challenging and competitive production market by minimizing stocks and throughput times, while maximizing on agility and accuracy.

2.5 Conclusion

These challenges will have severe consequences. They also put pharmaceutical companies under more pressure. The life science industry has already seen profits dwindle in last couple of years. Performance, Cost efficiency and Validation will be indispensable to comply with the demanding internal and external environment.

Deploying IBM Maximo Asset Management as a central automated maintenance management system will not only contribute to the compliance with industry regulations and standards, but will also prepare the company for tough challenges in the years to come.

3. Why is IBM Maximo the answer?

A valid question is why a centralised IBM Maximo asset management is a key component to meeting all these challenges. We have identified three drivers within the Life Science industry that IBM Maximo can support and enable the pharmaceutical to deal with the challenges ahead.

3.1 Decrease cost by investing in one system

Pharmaceuticals pay a high price when working with dissimilar installations of IBM Maximo, not sharing the same database or when not working with asset management software at all. The main reason for this is the lack of synergy that is missing because dispersed knowledge across locations cannot be leveraged in making business decisions. As a result, companies are overspending on turning raw data and information from reports and overviews into the craved for knowledge and wisdom. A centralised instance of IBM can be the source to a well-founded business decision.

3.2 Centralised IBM Maximo = Uniform Way of Working

Life Sciences companies that decide for one centralised and automated system will create consistency and harmonization within the company. One central IBM Maximo system will support in working with one overall vision for asset management for all locations, such as the risk-oriented manufacturing and quality processes that the FDA recommends. A centralised system results in a standard and interchangeable way of working in asset management including calibration, validation, scheduling leading to a more flexible, cost-effective and efficient organisation and less confusion of tongues amongst staff.

3.3 Consistency – Compliance against less risk

A centralised and automated IBM Maximo Asset Management system will also provide consistency because it enables the automation of the compliance-related activities. Overall consistency is required to be compliant with the Guidelines of the EMA[5] (EU-GCP/GMP) and the FDA[6]. Standardisation and centralisation deliver a valuable contribution when it comes to consistency, visibility and proving you are in control. It will also make staff more aware of the standard processes, procedures and workflows. Deciding to introduce one automated system will result in reduction of errors and compliance-related costs and risks.

3.4Conclusion

Moving to a centralised and automated IBM Maximo Asset Management system will not only prepare a company for the long term, it will also deliver direct results. Once compliance-related activities, risks are controlled and cost are reduced, investments can be made in, for example, the development of preventive healthcare treatments. Furthermore, existing and potential customers will be much more inclined to invest in relationships with partners that deliver consistency and accuracy. A centralised and automated system helps in delivering just that. Selecting IBM Maximo for this purpose goes without saying.

[5] European Medicine Agency
[6] Food and Drugs Agency

4. MACS and IBM Maximo partners in the Life Science Industry

4.1 IBM Maximo Life Science Solution

The IBM Maximo Asset Management solution has been widely used in the life science industry already. In more than 200 life science companies use IBM Maximo Asset Management. The IBM Maximo Life Science solution has been especially developed to support specific industry functionalities such as calibration of instruments and equipment, CAPA, inclusion of Compliance Assistance documentation. Further Maximo Asset Management out-of-the-box provides functionality that help in complying with FDA regulations, such as the capability to support electronic signatures. The solution's ability to track and monitor changes also enhances the ability to address compliance regulations and to more efficiently support validation projects.
The dedication of IBM into the Maximo Asset Management for Life Science will continue to grow. As such, it will provide a sound foundation for meeting the upcoming challenges.

4.2 MACS and IBM Maximo Life Science

Not each IBM Maximo business partner will have affinity and experience with the Life Science Industry and the specifically the pharmaceutical industry. MACS has been working with almost 10 customers in the life science industry, of which 5 are pharmaceuticals. Over the years, MACS management and staff have gained extensive experience within the Life Science industry including pharmaceuticals and the industry specific regulations. Submersion in the industry's requirements and practices has been especially useful with compliance-related subjects. The area of validation has shown stringent application of the Computer System Validation Practice of EMA and FDA.

4.3 Customers using IBM Maximo

MACS has noticed the interest in the industry to move to one central IBM Maximo system and has actively responded to this trend. Some clients chose to move European locations to one system and while others moved locations to a worldwide system. In all cases consistency, compliance, cost or standardisation were key drivers. IBM Maximo's reporting ability added relevant functionality to all clients when it comes to bench marking and improvement of different elements relating to maintenance and asset management. The possibility to align and automate IBM Maximo according to the best practice and the regulations of the FDA and the European equivalent EMA has been supportive in the software selection. Finally, add-on industry solutions as IBM Maximo Calibration have been also a strong driver with MACS clients to select the product.
In short, both the specific industry solutions and the capability to centralise and automate the regulated international processes have been compelling reasons for clients to deploy IBM Maximo.

About MACS

MACS provides IBM Maximo Asset Management services to five leading pharmaceutical organisations across Europe.

MACS provides IBM Maximo Asset Management services to five leading pharmaceutical organisations across Europe. The MACS Holding company, established in 1998, employs staff in Netherlands, Belgium, Germany and United Kingdom. MACS provides professional services with a broad experience of implementing solutions for Maintenance Management, Asset Management and IT Service Management. A long standing premier IBM Business Partner distributing IBM Maximo Asset Management and IBM Tririga software across the regional offices.

Further information about MACS can be found at: http://www.macseu.co.uk

About IBM

IBM Maximo Asset Management is a world renowned software product. The IBM Maximo Enterprise Asset Management solution unifies comprehensive asset life cycle and maintenance management on a single platform, providing insight into all of an organization's enterprise assets, their conditions and work processes to achieve better planning and control. IBM Maximo also includes specific industries solutions such as for the Life Science industry.

Further information about IBM Maximo Life Science can be found at:

IBM Maximo

References

- European Medicines Agency, 2012, Good Manufacturing Practice and Good Manufacturing Compliance. Available from: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000154.jsp&mid=WC0b01ac0580027088
- FDA, 2014, Code of Regulations. Title 21, Available from: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm
- IBM, 2011, Unified Management supports the convergence of health ca re assets. IBM Maximo Asset Management addresses patient care, facilities and technology challenges. IBM Software, Thought Leadership Whitepaper, Available from:http://public.dhe.ibm.com/common/ssi/ecm/en/tiw14114usen/TIW14114USEN.PDFWhite Paper
- PWC, 2012, From Vision to Decision. Pharma 2020. Available from: http://www.pwc.com/en_GX/gx/pharma-life-sciences/pharma2020/assets/pwc-pharma-success-strategies.pdf
- PWC, 2012, Disruptive Innovation in a Converging Health Market. Available from: https://www.youtube.com/watch?v=RoLomumfLfk