Healthcare industry BW

Pharma 2.0: towards paperless production

Before electronic solutions existed, lorries were needed to ship new drug applications, which often comprised 500,000 or so pages. Thanks to IT, this is no longer necessary. IT-based procedures and solutions are playing an increasing role in all areas of the pharmaceutical industry. New IT technologies are constantly being developed for the different production steps, and legal guidelines are constantly being expanded. Markus Roemer, CEO of Ravensburg-based "comes compliance services" supports companies in implementing these guidelines. In the following interview, Roemer talks about new developments related to paperless production processes and the challenges that these developments represent for companies.

Markus Roemer, managing director of 'comes compliance services'
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Mr. Roemer, why is the pharmaceutical industry increasingly using IT?

There are two major reasons for this: efficiency and transparency. An excellent example of the use of modern IT is the drug applications that are sent to regulatory authorities. Drug applications usually comprise around 500,000 pages and previously had to be delivered by lorry. With the advent of electronic signatures, the applications can now be sent electronically. Another example is e-reporting: when a drug that has been authorized for commercialization is later found to cause severe adverse effects, the manufacturer of the drug is contacted. IT, in this case e-reporting, then enables the manufacturer to release information about the drug's adverse reactions without delay and immediately warn other patients throughout Europe. Such a process previously took several days.

Are there any new guidelines related to the application of IT in the pharmaceutical industry?

From a regulatory point of view, 2011 can be seen as an exciting and innovative year as far as the application of IT in the pharmaceutical industry is concerned. And this will continue in the future where the major focus will be on product and patient safety. For example, some chapters of the EU-GMP (good manufacturing practice) guideline relating to documentation and computer-based systems have been revised in the light of the increasing use of electronic documents within the GMP environment. In addition, the new legislation on falsified medicines (2011/62/EU) introduces tougher rules to stop counterfeit medicines entering the legal supply chain. The 16th Amendment of the German Drug Law has made reporting requirements tougher through pharmacovigilance guidelines. To this end, the EU has established a central online database (EudraVigilance) designed to manage safety reporting information, the e-reporting I mentioned above.

Have the individual steps relating to drug development and approval changed?

As far as the seeking of marketing authorization for new drugs is concerned, in March 2012 the European Medicines Agency (EMA) launched a pilot scheme that allows pharmaceutical companies to submit new drug applications electronically (in pdf form). In addition, the new quality paradigm of the ICH (International

Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) is of key importance in GMP environments; based on an integrated approach to quality risk management and science, it seeks to develop a harmonized pharmaceutical quality system that is applicable across the lifecycle of a product. For example, production and quality records or batch protocols will be recorded and released electronically to a much greater extent than in the past. The draft of the new EU-GDP (good distribution practice) guideline has grown from around four pages in 1993 to around 32 and now also includes requirements on purchase, receiving and storage of drugs intended for human consumption, as well as cool chain management (surveillance) and the requirement for products (packages) to have defined safety properties. What these examples have in common is that they are implemented using smart IT solutions and concepts that still need to be validated. This then generates transparency and compliance as well as a higher operative value in that it reduces throughput time and improves the supply chain process.

What kind of challenges arise from the practical implementation of the legal requirements related to the use of IT in the pharmaceutical industry?

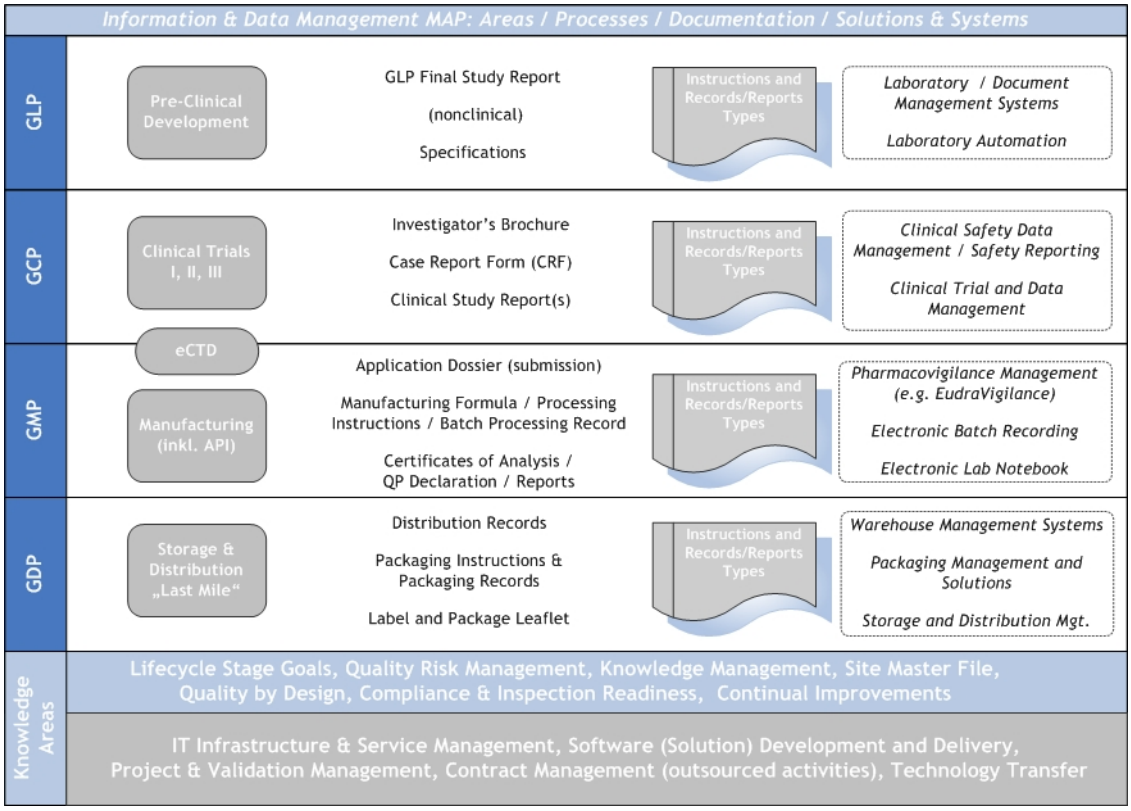
As the motto "IT meets Pharma" shows, this is a meeting between two different disciplines and competences. Formulating the requirements, finding correct IT solutions and concepts, integrating and validating them is a huge challenge. We are talking about IT solutions and concepts, not just IT systems or basic technologies. Cool chain management can be technologically solved by way of RFID (radio frequency identification) technology, which is a wireless identification and tracking method that uses radio-frequency electromagnetic fields to transfer data. In addition, safety characteristics can be implemented by way of micro text, data matrix code or hologrammes. The replacement of paper-based processes with electronic solutions is associated with such issues as whether electronic signatures have the same validity as a handwritten signature. Other issues are safety aspects and their organizational implementation in a qualified network or the changes to and optimization of the – validated – processes themselves.

Do big pharmaceutical and small and medium-sized companies approach the issue differently, are there differences in how these companies implement the guidelines?

IT methods are well established in "Big Pharma". The providers of the solutions might not be that close to the respective company's operative business; but nevertheless the solutions are there. The situation is different in small and medium-sized companies; although there is greater closeness, the methods are not always so established. These methods may be helpful and help save time but cannot generally guarantee a successful outcome for projects.

Are these methods and standards general across the board?

According to the requirements of the GMP guidelines amongst others, specification documents must be compiled within a quality management system. The implementation concepts are sometimes defined rather generally, which makes it necessary to adapt them to different issues and areas. Validated systems generate relevant data and information, which are used as the basis for decisions made by specific people in a specific information channel (roles and responsibilities). In addition, as you can see in the figure below, it is also important to take into account interprocess links (information and system interfaces): a clinical trial report can become part of the drug marketing authorization dossier; a "qualified person" (ed. note: as stipulated in Article 48 of Directive 2001/83/EC and Article 52 of Directive 2001/82/EC) can then release batches on the basis of the stipulations made in the dossier.



The schematic shows the individual steps in the drug development process in relation to applicable guidelines, work processes, documentation systems and implementation concepts. The individual steps are governed by the following guidelines: GLP (good laboratory practice), GCP (good clinical practice), GMP (good manufacturing practice) and GDP (good distribution practice). The last two rows show fields of knowledge that play a role in improving the production process.

How does "comes compliance services" support the pharmaceutical industry in the implementation of quality standards and in the shift towards paperless systems and processes?

CCS is a consulting company with project teams consisting of experts and network partners who provide and accompany such project concepts, who work with and implement the respective IT solutions. We are specialized and highly experienced in the implementation of electronic solutions. For example, over the last three years we have been involved in more than 20 document management and electronic batch recording projects. Based on our detailed knowledge of the regulatory requirements and technical solutions, we can professionally support and implement interdisciplinarily tried and tested project methods.

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