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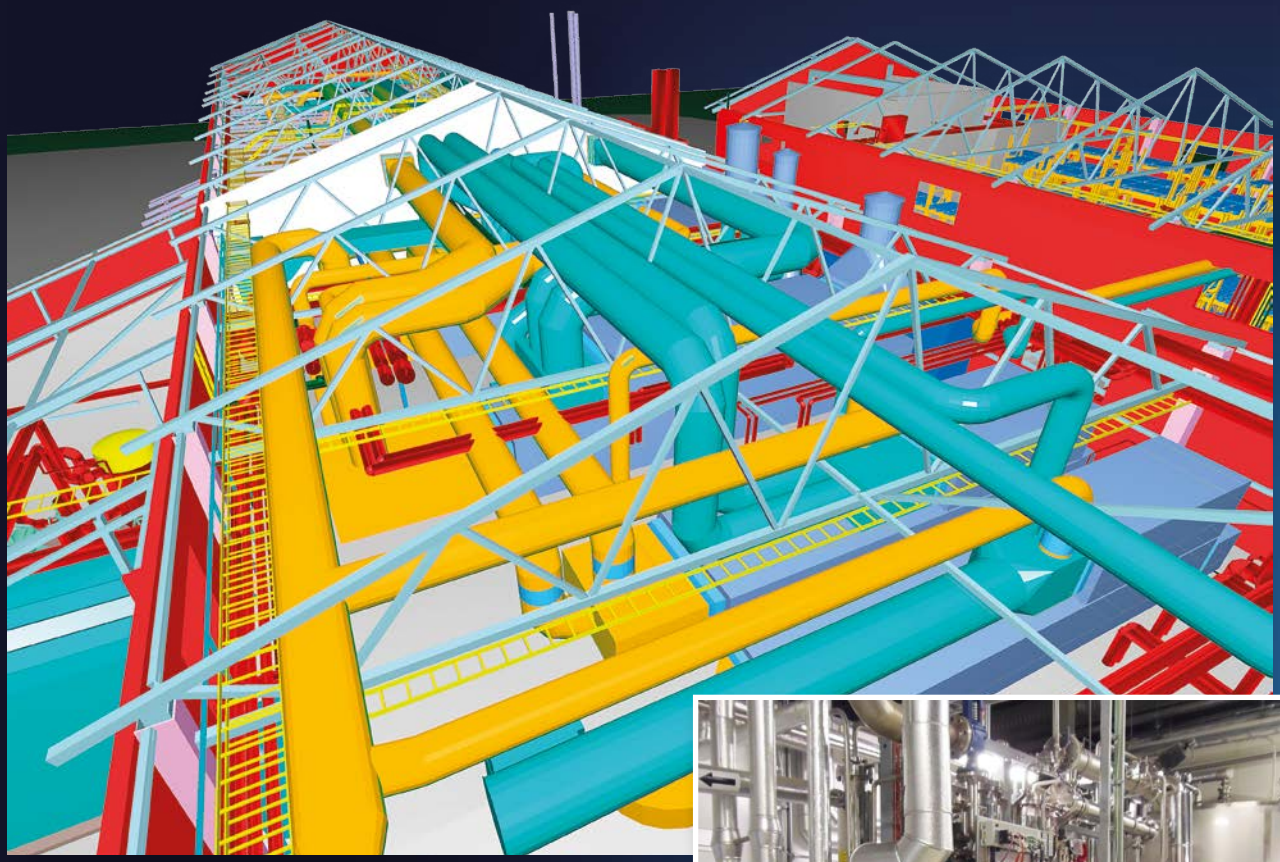
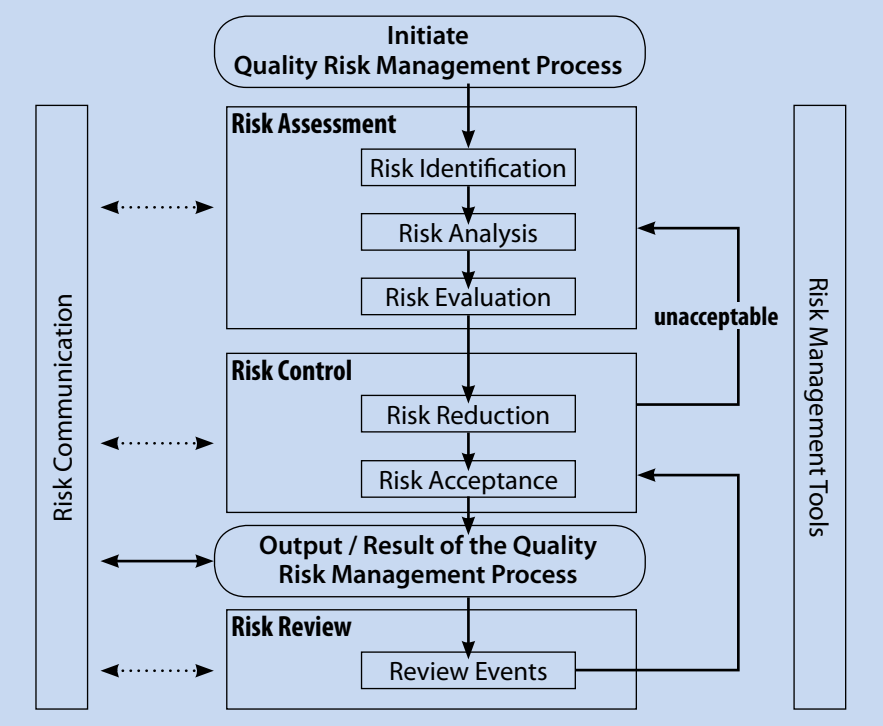


GMP Services

– expert services that keep you in control



A typical quality risk management process (ICH Q9)

Example

Drawing up a risk-based particle monitoring plan for a sterile manufacturing facility

Elomatic was engaged to plan and draw up a risk-based monitoring plan for non-viable particles according to ISO 14644-2:2015 for a customer's sterile manufacturing facility. The methods applied in the project were a causal method (Ishikawa) + 6M to identify the root causes for particles in the air, followed by an FMEA to determine the probability and severity of the existence of particles in the air from the sterile product's perspective. The outcomes of the project were a documented risk analysis and a draft particle monitoring plan.

Pharmaceutical products have to be safe for the patients taking them. To ensure patient safety, rules or principles that govern the manufacture of pharmaceutical products are in place. These principles are usually referred to as "minimum requirements", but what does this mean in practice?

GMP is a (relatively) simple-to-understand set of principles concerning various aspects of pharmaceutical manufacturing and distribution operations. The authorities expect pharmaceutical manufacturers to comply with these "minimum requirements" in order to prove that they consistently supply products that are suited for their intended use. Proof of this is provided by means of documentation.

Be in Control

Complying with minimum requirements indicates to "someone else" that the rules are being followed. On the other hand, being in control of patient safety means that one understands the risks connected to processes and products and that the measures necessary to ensure being in control of these risks have been taken, and will be taken. The regulators want manufacturers to be in control! Therefore, *risk management* has become increasingly common in regulators' texts. They also want to be assured that manufacturers operate in a systematic and correct manner, and therefore, *documentation* is required.

Quality risk management

Risk management is not a new term per se, but the pharmaceutical industry has put more emphasis on it during the 21st century. The ICH guideline Q9 on quality risk management was published in 2006. In response to this, the ISPE Baseline Guide Volume 7: Risk-Based Manufacture of Pharma Products was updated to its second edition.

Chapters of EU GMP

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Regulations and standards from

- FDA
- EMA
- FIMEA
- PMDA (Japan)
- CDSCO (India)
- ICH
- ISPE
- ISO

Quality risk management can be applied to various aspects of operations, e.g. design of facilities, equipment and utilities, or change management. A wide variety of tools can be used for risk management, but the most common in the pharmaceutical industry today seems to be FMEA (Failure Mode Effects Analysis), or some variations of this method.

Elomatic has experience in applying risk management procedures for different purposes. The methods applied are usually selected together with the customer, but we always provide our own suggestions as to what methodology would be the most suited.

Documentation

There are certain rules that need to be adhered to in order to produce good documentation. One of the most important is to always consider the reader, when writing a document. The document should contain everything necessary, but also be as concise and easy to read as possible.

Elomatic can assist customers to plan and draw up documentation related to various areas of GMP. We have decades of experience in handling and drawing up documents for the biotech and pharmaceutical industry. Therefore, we understand the specifics of the operational environment – including the authorities' expectations of the level and quality of documentation. It should be noted that Elomatic – as an engineering company – is mainly focused on matters relating to the premises and equipment, but we can also provide support regarding other areas of GMP.

We want our customers to be in control of their GMP operations!

Are you in compliance with minimum requirements or are you in control?

ELOMATIC
CONSULTING & ENGINEERING

Elomatic is a leading European consulting and engineering company. Our close to 1000 professionals work in machinery and equipment manufacturing, pharmaceutical, process, energy, offshore and marine industry projects.

We offer consulting, engineering, product development and project management services as well as products and turnkey solutions to industrial and public sector customers.

The cornerstones of our success are customers that are leaders in their respective fields and professional, customer-oriented and motivated personnel.

- Technical Consulting
- Engineering
- Project Management
- Product and Service Development
- Products & Turnkey Solutions
- Software Development
- Design Software Solutions

Key customer segments

- Marine & Offshore
- Oil & Gas
- Pharmaceuticals
- Process Industries
- Energy
- Foodstuffs industry
- Starch and Potato Processing
- Machinery and Equipment Manufacturing

Contact information

We operate globally and have clients in over 80 countries. Our offices are located in Finland, China, India, Italy, Kazakhstan, the Netherlands, Poland, Russia and the UAE.

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