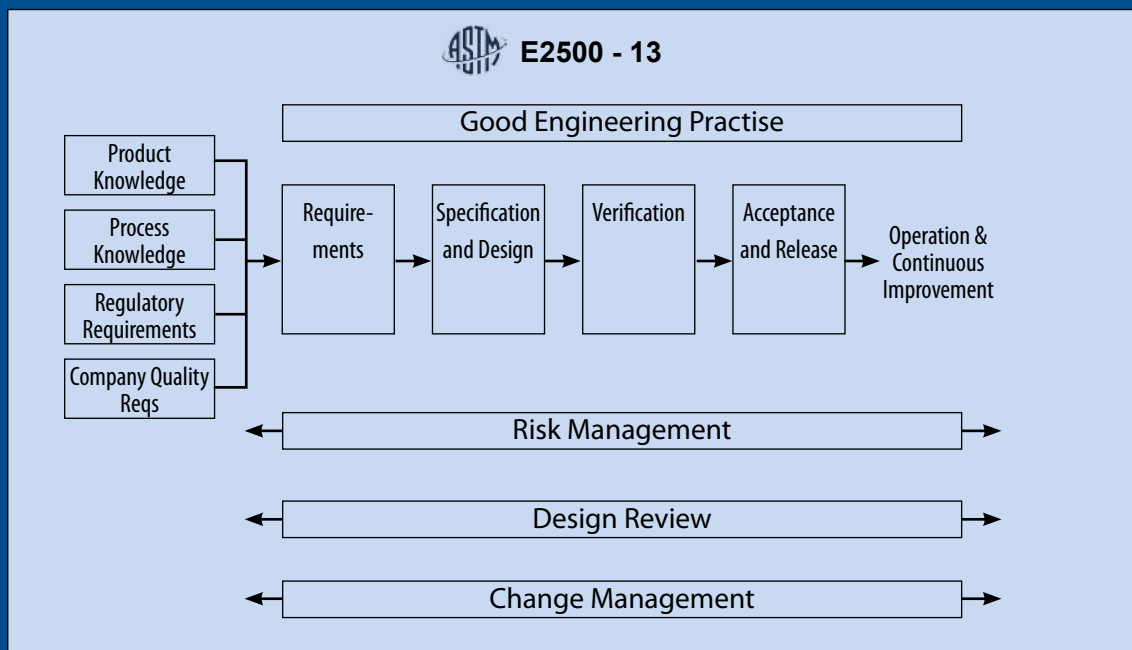


Verification

– well planned is half done



Specification, Design, and Verification Process acc. to ASTM E2500 – 13.

Elomatic's unique know-how combines a thorough understanding of Good Manufacturing Practices (GMPs) with a profound knowledge of the technical details of pharmaceutical manufacturing facilities and systems. We have gained our experience from numerous projects executed in many countries during the past three decades.

There is an ongoing shift in terminology, where the terms *commissioning*, *qualification* and *validation* are jointly being called *verification* (refer to e.g. ASTM E2500 - 13). When handled correctly, verification is an integral part of project management. Elomatic's focus on projects is to save costs and avoid delays by managing the project as efficiently as possible, e.g. from forward traceability from user requirements all the way to final verification activities. Binders

can also be planned beforehand, and documentation is in place from the very beginning of the project.

Elomatic ensures that there are fewer quality issues and surprises at later stages of investment projects as we take a proactive, systematic and pragmatic approach to the project at hand. The sooner errors and deficiencies are identified, the bigger the cost savings are.

URS

The User Requirements Specification is a very important document when planning a new manufacturing facility, system or piece of equipment. It is the **user's** written thoughts of what is needed. The URS should contain all information necessary (quality, capacity etc.) for a supplier or contractor to be able to suggest a suitable design. The URS forms the basis for all verification activities and it should be referenced throughout the project life cycle.

Example project

Implementation and validation of a new automation system

The customer needed a new control system for its water distribution system. Elomatic was engaged to design, implement and validate the system. First, written specifications (user requirements) were drawn up.

Based on these specifications, the design and implementation work was carried out. Commissioning and qualification protocols were drawn up, including the required testing to show conformance with the specifications. The customer was given system training and the project was completed with commissioning testing and qualification summaries and reporting.

Contact



Tony Lönnbäck
Senior Consulting Engineer
HSE services
Tel. +358 2 412 4331
Mob. +358 40 507 9852
tony.lonnback@elomatic.com

Elomatic's services

- Overall project planning
- System specification (e.g. URS)
- System design
- Execution of verification activities (commissioning, qualification, validation)
- Reporting of verification activities

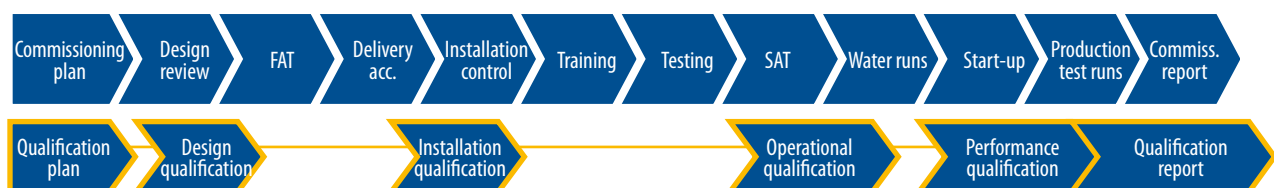
Validation (qualification)

- URS (User Requirements Specification)
- DQ (Design Qualification)
- IQ (Installation Qualification)
- OQ (Operational Qualification)
- PQ (Performance Qualification)
- PV (Process Validation)

Commissioning

- DR (Design Review)
- FAT (Factory Acceptance Test)
- SAT (Site Acceptance Test)

The ASTM E2500 - 13 standard was drawn up in response to the FDA's initiative Pharmaceutical cGMPs for the 21st Century – A Risk-Based Approach. According to this approach, more emphasis is put on an understanding of the process in the specification, design and verification phases. Quality is built into this process e.g. by relying more on GEP (Good Engineering Practice) and SMEs (Subject Matter Experts), and by applying design reviews as a process throughout the project life cycle instead of it being an isolated event.



Verification = Commissioning, Qualification, Validation



Elomatic is a leading European consulting and engineering company. Our close to 900 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

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

Contact information

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

Elomatic – Headquarters
Itäinen Rantakatu 72, 20810 Turku, Finland
Tel. +358 (0)2 412 411
info@elomatic.com

www.elomatic.com