



IMPROVING PROCESS AND PERFORMANCE THROUGH
ASEPTIC PROCESSING COMPETENCIES



Solutions that Improve Efficiency & Productivity

With regulatory agencies focusing on aseptic processing, many Life Sciences companies organizations are taking extra steps to define and assess the skills of those working in aseptic manufacturing. With studies showing the measurable value of competency and skills mapping, UL's Aseptic Processing solutions includes hands-on GMP consulting expert Ann Early to work alongside your QA, Training, HR and Operations team to build a program that's based on proven best practices.



Questions that QA and Operations Teams Are Posing About Aseptic Processing:

How can we reduce risks due to aseptic behavior?

How can we map specific competencies around sterilized manufacturing, environmental monitoring, and other areas, so that each job function is properly trained?

How can we improve the quality culture in our organization so that employees and contractors are motivated to take the right steps in the cleanroom?

How can we gain better visibility into our training programs, and deliver a more effective training experience?

Focus on Competency Management

Competency Management is a systematic approach that captures skills and behaviors of employees for each job function. Having an inventory of "skill definitions" can improve the company's ability to recruit and manage succession planning.

With a competency model in place, employees can acquire and maintain the skills and knowledge needed to perform a job to defined standards.

The development of meaningful skill evaluation and competency management is becoming increasingly scrutinized by US FDA and other global agencies during inspections. Even standards such as ISO 13485: 2016 are now requiring a formal competency management plan in place.

Elements of Our Solution

Choose the element you need, from improving quality culture to competency mapping

Our expertise can be provided at a single facility or multiple facilities, clients can build a skills development framework that follows a seven-step process shown here, shown below.

These steps map relevant, competency-based actions that need to be conducted for each job function. Companies can achieve compliance while improving business performance, and also drive these improvements:

- Greater employee knowledge related to the basics of microbiology, aseptic gowning, and aseptic behavior
- Increased employee engagement through well-defined roles and job functions

FDA CITES LACK OF VALIDATION OF ASEPTIC PROCESSES IN 2015

According to US FDA, "Validation of aseptic processes including sterilization" was the fourth-most cited 483 observation in 2015, with 157 observations recorded (211.113(b)).



- Understanding of measurement best practices, such as incidence rate of personnel monitoring and production line environmental monitoring failures, deviation reports, and lot rejection rates

- Improved gowning and aseptic behavior

Our solution includes these elements, which you can select based on your current experience:

- Conducting an Initial Assessment
- Building a Competency Master File
- Mapping Competency Proficiency Levels (Beginner, Intermediate, Master)
- Developing and Delivering the Competency Assessment
- Gap Analysis and Development Programs
- Measurement and Monitoring Best Practices







Improve aseptic techniques, cleanroom behavior, compliance and productivity

Contact UL today to learn how our Aseptic Processing solutions can impact your compliance objective and your business performance goals. Contact any of our local offices:

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About UL Compliance to Performance

UL Compliance to Performance provides knowledge and expertise that empowers Life Sciences organizations globally to accelerate growth and move from compliance to performance. Our solutions help companies enter new markets, manage compliance, optimize quality and elevate performance by supporting processes at every stage of a company's evolution. UL provides a powerful combination of advisory solutions with a strong modular SaaS backbone that features ComplianceWire®, our award-winning learning and performance platform.

UL is a premier global independent safety science company that has championed progress for 120 years. It's more than 12,000 professionals are guided by the UL mission to promote safe working and living environments for all people.

For more than 30 years, UL Compliance to Performance has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university. Additionally, UL maintains exclusive partnerships with leading regulatory and industry trade organizations.

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