SfSAP
society for sterility assurance professionals

Pathways to develop expertise in different sterilization modalities by acquiring knowledge, skills, and experiences.

LEARNING FRAMEWORKS AND OUTCOMES

USER GUIDE

Document Number UG0001 Version 2 16.2.25

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What is SfSAP?

The Society for Sterility Assurance Professionals has been established as a collaborative not-for-profit initiative and supported by the iia, AAMI, and PDA. It aims to enable the medical device and pharmaceutical industries to formulate a standard approach to meeting the requirements of Medical Device Regulations (MDR), ISO 13485:2016, and other relevant regulations such as Good Manufacturing Practices (GMPs). The Society has a formal constitution and has been created as a legal entity in the United Kingdom. A board of directors provides oversight of strategic matters while a steering committee co-ordinates all collaborative initiatives and the formation of working groups. Members of the working groups work together developing the required output (e.g., learning frameworks) and guidance in their area of expertise.

Founding principles of SfSAP

The Society for Sterility Assurance Professionals (SfSAP) is a professional association dedicated to the advancement of Sterility Assurance for medical and pharmaceutical products.

The founding principles of the SfSAP are:

VISION

SfSAP will focus on defining the competency of Sterility Assurance professionals. It aims to collaborate with education delivery organisations (EDOs) and is working to ensure that Sterility Assurance professionals have access to a record keeping system.

COMPETENCY

Global experts in SfSAP working groups have worked together to identify the knowledge, skills, and experiences that a person needs to demonstrate based on the individual's role in the lifecycle of the sterilization modality.

COLLABORATION

SfSAP encourages better coordination in the training, testing, and development of Sterility Assurance professionals through a competency framework.

COMMUNITY

SfSAP supports individuals in achieving their development goals and the needs of the healthcare community in the field of Sterility Assurance.

CONNECTION

SfSAP helps members of the community to build networks in order to achieve their career development goals and the needs of the wider healthcare community.

CAREER

SfSAP has created a pathway for those involved in Sterility Assurance and in the sterilization of medical and pharmaceutical products as individuals move from novice to competent to proficient to experts.

Developing competency through collaboration

SfSAP sees four key groups or stakeholders that can benefit from SfSAP's efforts. In some cases, an organization may fit into more than one group. For example, a contract sterilizer may also be an educational delivery organization (EDO) as it provides hands-on experiences to manufacturers. A manufacturer or regulator may also be an EDO for its personnel.

Modalities of sterilization

Sterilization is any process that removes, kills, or deactivates microbes like bacteria, molds, fungi, and viruses. This is critical for medical supplies, medical devices, and injectable (or low bioburden) pharmaceutical products in order to protect the safety and health of those that use such products. For something to be sterile, it must be free of micro-organisms.

Modalities of sterilization refers to the different methods available, including:

- Moist heat
- Radiation
- Ethylene oxide gas

Supporting sterilization requires other Sterility Assurance professionals such as microbiologists who test products and identify organisms found during environmental monitoring, packaging experts who test and assure that packages and containers do not allow the ingress of microbial contaminants, and auditors and health authority inspectors who evaluate the effectiveness and performance of such operations.

Aseptic processing, while not a sterilization modality, does result in sterile drug and biological products. This is accomplished by sterilizing the components (e.g., containers, closures, drug product) separately and bringing them all together for assembly in an aseptic environment like an isolator and using proper aseptic techniques in order to maintain their sterility.

SfSAP working groups

Several working groups with the SfSAP organization have been formed to create the learning frameworks and outcomes as well as to provide other support for these efforts. These working groups, comprised of international volunteers, are:

- SfSAP steering committee
- Microbiology
- Aseptic processing
- Ethylene oxide gas
- Packaging / sterile barrier systems
- Bio-compatibility
- Regulatory / health authorities
- Moist heat
- Radiation

Why these learning frameworks were created

The SfSAP learning frameworks were developed by an international set of experts that are involved in producing and supporting the production of sterile products in order to:

- Present a "roadmap" of the knowledge, skills, and experiences that should be acquired by an individual wanting a career as a Sterility Assurance professional.
- Guide organizations in the knowledge, skills, and experience they should look for when hiring a Sterility Assurance professional.
- Identify the goals, learning objectives, topics, and reference sources that should be included in training / educational modules offered by educational or training organizations that offer learning opportunities in the field of Sterility Assurance.
- Provide a set of expectations that can assist auditors and health authority inspectors.
- Contribute to knowledge management by communicating explicit knowledge through education and training and the sharing of tacit knowledge through hands-on work and experiences.

The progression from novice to expert

Becoming an expert in any field does not happen in a year or two. It takes a combination of foundational knowledge, specific training in a field, and then a series of experiences such as writing or reviewing standards, providing training, and solving a variety of problems. The learning frameworks include all of these ways of acquiring knowledge, skills, and experiences.

Frameworks available

The list below shows the learning frameworks that the teams of international experts have been developing.

Microbiology, bio-compatibility, and packaging/sterile barrier systems are important as they support the different sterilization modalities and need to be assessed before products can be commercialized and put on the market.

- Microbiology
- Aseptic processing
- Moist heat
- Radiation
- Ethylene oxide gas
- Packaging / sterile barrier system

A work in progress

As the expert teams have been developing the frameworks, the information that they include and how that information is presented have been changing. Additionally, the SfSAP learning model is also evolving, for example, identifying different roles (job positions) and using a step-wise progression in moving through the topics. The frameworks will be updated as needed, taking into consideration findings by health authorities and quality auditors that find knowledge and skill deficiencies. This means that the learning frameworks are being improved as we get more experience with them through comments from experts and learners alike. We also envision that a future version of the learning frameworks will distinguish between "core" topics – those that apply to all people involved in a sterilization modality and "supplemental" topics – those that would be applicable to persons wanting to focus on a particular facet of the modality, for instance, operations, quality, validation, facility design, etc.

Keeping up-to-date

In addition to this document, as SfSAP makes organizational and structural changes and the working teams revise and complete progress in their frameworks, "addenda" with updated information will be prepared and will be included in revisions to this published document. All published SfSAP documents are available on the SfSAP website along with an addenda that will identify any updates and/or corrections to published material. Users should ensure that they check the addenda regularly.

What the typical framework includes:

The table below is an example of a page taken from the Learning Framework for Radiation. See corresponding annotated numbers with details on the right.

Healthcare Products Radiation Sterilization Learning Outcomes

DOCUMENT NUMBER: RHLO001
Revision: 2

Framework Category / Module			
Maximum acceptable dose: ISO 11137 Parts 1, 3 and 4, AAMI TIR 17, AAMI TIR104, Panel Guide on the establishment of the maximum acceptable dose (Dmax,acc) for a product			
Knowledge & Skills Required	**Learning Outcome** (What person should be able to do with the knowledge & skills)	**How were K&S acquired** 1. Formal course 2. Reading / self-study 3. Structured on-the-job 4. Other (specify)	**How were K&S assessed & documented?** 1. Written test 2. Discussion with SME 3. Demonstration of performance 4. Confirmation by SME or supervisor 5. Other (specify)
Requirements for determining the maximum acceptable dose	**LEVEL 100** • Describe the definition of D_{max} • Describe the definition of $D_{max,acc}$ • Explain the difference between D_{max} and $D_{max,acc}$ • Outline methods for the determination of Dmax,acc		
Requirements for determining sample size, delivering dose(s) to the samples, and use throughout product shelf life after exposure	**LEVEL 200** • Identify the concepts in "Panel Guide on the establishment of the maximum acceptable dose ($D_{max,acc}$) for a product" in determining sample size • Describe the definition of dose uniformity • Outline methods that can be used to minimise the Dose Uniformity • Describe Process capability with regards to dose range to achieve a precision dose required for Dmax,acc • Explain the rationale for tiered testing of the $D_{max,acc}$		

1. **The framework category.** Core foundational Facilities, operations, processing, Sterility Assurance.
Module is a set of related topics.

2. **Reference documents** are the primary source materials that are the basis for this module. This information may be supplemented with other relevant examples and articles selected by the instructor.

3. **Knowledge & skills required** is a list of the topics that have been identified by the expert teams that a Sterility Assurance professional should know or be able to perform. These can help guide learners as they read through the reference documents.

4. **Learning outcomes** are behavioral statements of how someone would use the knowledge and skills. They can be considered learning objectives. As the frameworks evolve, the learning outcomes number-coded as shown here:

   100 Level – foundational outcomes, best associated with a person transitioning from a new hire/novice to competent

   200 Level – advanced outcomes best associated with a person transitioning from competent to proficient

   300 Level / EXP – outcomes derived primarily from experiences, best associated with a person transitioning from proficient to expert

5. **How were knowledge & skills acquired?** is the method(s) that the learner used to obtain the knowledge and skills and achieve the learning outcome.

6. **How were K&S assessed and documented?** that provides confidence to stakeholders that that learner has successfully acquired the knowledge and skills and accomplished the learning outcome.

How to use the learning framework: Individuals

If you are an individual on the pathway to becoming a Sterility Assurance professional, here is how you can use the Learning Framework.

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1. **Module.** When looking for a training course or event, this title may be useful in your search.

2. **Reference documents** are the primary source materials that are the basis for this module. This information may be supplemented with other relevant examples and articles selected by the instructor.

3. **Knowledge & skills required** are the topics that are important for a Sterility Assurance professional to know or be able to perform in regards to this module. If you are searching for a training course, look to see if these topics are included in the course outline. These topics may not be found in one specific course; rather, they may be contained in different courses or modules.

4. **Learning outcomes** are the activities you would need to complete and be able to demonstrate to show that you have acquired the defined knowledge and skills. In some cases (e.g., describe or discuss) you would demonstrate your knowledge and skills by talking to an instructor, a more knowledgeable expert or sometimes demonstrating performance. Or, you could write a paragraph or two that is assessed by an instructor. In other cases, a learning outcome might be demonstrated by completing a task.

5. **How were knowledge & skills acquired?** There are a variety of ways that knowledge and skills can be obtained. Early in one's career it may be formal or on-the-job training while later, experiences are major contributors.

6. **How were K&S assessed and documented?** identifies how one demonstrated and provided documentation of meeting the learning outcome. It might include a certificate of accomplishment or a confirmation by a mentor or other expert. SfSAP is looking to provide an online system to house and share this information.

How to use the learning framework: Education delivery organizations (EDOs)

If you provide education or training to support the development of Sterility Assurance professionals, here are some ways you can use the Learning Frameworks. (If a manufacturer provides training for its personnel it could also be considered an EDO.)

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1. **Module.** Consider arranging your training courses or sessions using the module name.
2. **Reference documents** are the primary source materials that are the basis for this module. This information may be supplemented with other relevant examples and articles selected by the instructor.
3. **Knowledge & skills required.** Consider having these topics specifically included in the description of your courses and in the course outlines.
4. **Learning outcomes** are the behavioral objectives to cover as you design and implement the training. A variety of assessment approaches can be used including have learners work on case studies, do "on the job" projects, or discuss with knowledgeable experts. Quizzes or tests can also be used but try to avoid simple multiple choice or fill-in type methods.
5. **How were K&S assessed and documented?** is where the EDO provides support that the learning outcomes were achieved.

How to use the learning framework: Manufacturer, service provider, contract sterilizer

If your organization produces sterile products or provides a related service (e.g., microbiology laboratory), here are some ways that you might use the Learning Frameworks.

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1 **Module.** Consider arranging your training courses or sessions using the module name.

2 **Reference documents** are important to be able to access when developing processes, writing procedures, providing training, or perform audits/inspections. Be sure the most current versions are available.

3 **Knowledge & skills required.** If you are hiring a Sterility Assurance professional, look to see if they have the knowledge and skills listed here.

Few people have all of these, so look across your organization to see if collectively your organization has these.

4 **Learning outcomes** are ways that people should be able to demonstrate they have the knowledge and skills listed. This may come from training or, more practically, experiences that they have had.

During an interview, you might find it valuable to discuss the topics or have someone describe how they have accomplished the outcome in a real-life situation.

How to use the learning framework: Health authorities / regulators

Regulations require that personnel are competent to do their jobs by having the relevant education, training, and experience. Health authorities can use the Learning Frameworks in two different ways:

(1) Seeing what industry experts consider being relevant as individuals develop their expertise and

(2) Ideas to include in the training of inspectors and auditors.

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1 **Module.** Consider arranging your training courses or sessions using the module name.

2 **Reference documents** are important to be able to access when developing processes, writing procedures, providing training, or perform audits/inspections. Be sure the most current versions are available.

3 **Knowledge & skills required.** When inspecting or auditing, determine if the firm has an individual or a team with these competencies based on the people's roles.

When providing learning opportunities to inspectors or auditors, consider this set of knowledge, skills, and behaviors that are important for inspectors and auditors to have.

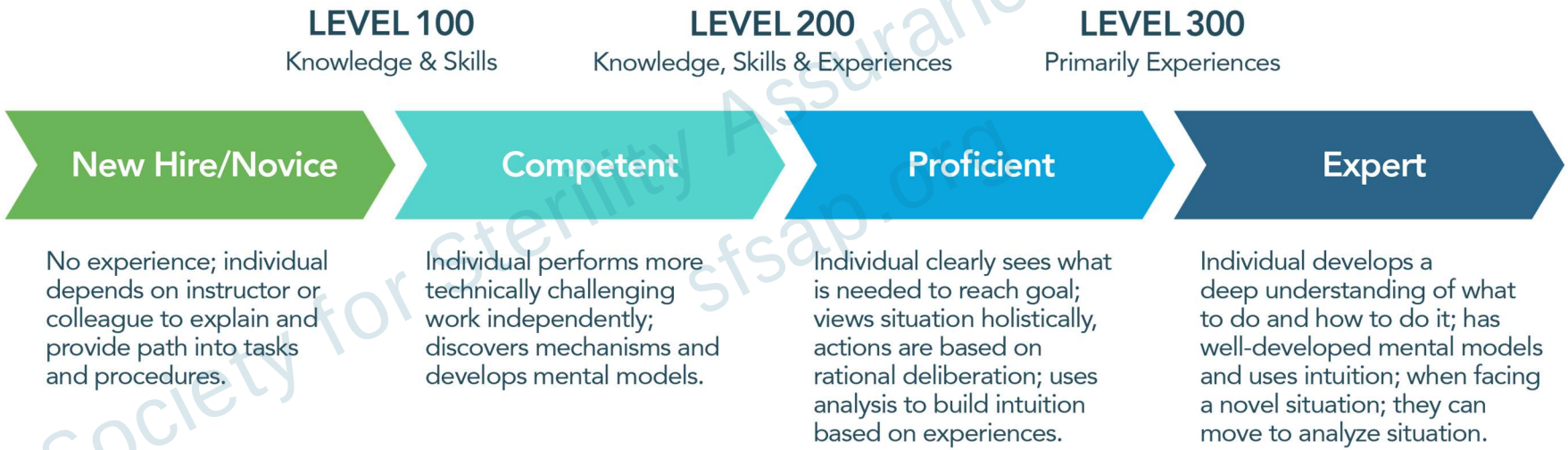
4 **Learning outcomes** are ways that people should be able to demonstrate they have the knowledge and skills listed. This may come from training or, more practically, experiences that they have had.

During an interview, you might find it valuable to discuss the topics or have someone describe how they have accomplished the outcome in a real-life situation.

SfSAP Approach: Moving from novice to expert

It takes time for someone to acquire the knowledge and skills to move from novice to the more advanced levels of competent, proficient, and expert. Becoming an expert requires a person to have years (often said to be 10 years) and hundreds of different experiences. It is important to note that *not everyone needs to become an expert* – our industry needs people who are competent and proficient. The SfSAP learning frameworks are intended to guide individuals to the level of mastery that they want to achieve.

Here is a diagram* that shows and describes the progression.



*Based on the Dreyfus and Dreyfus Skill Acquisition Model

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