A Structured Pathway to Support, Attract, Retain, and Develop Professionals Involved in End-to-End Sterility

Arthur Dumba &

James Vesper, PhD, MPH

Society for Sterility Assurance Professionals (SfSAP)

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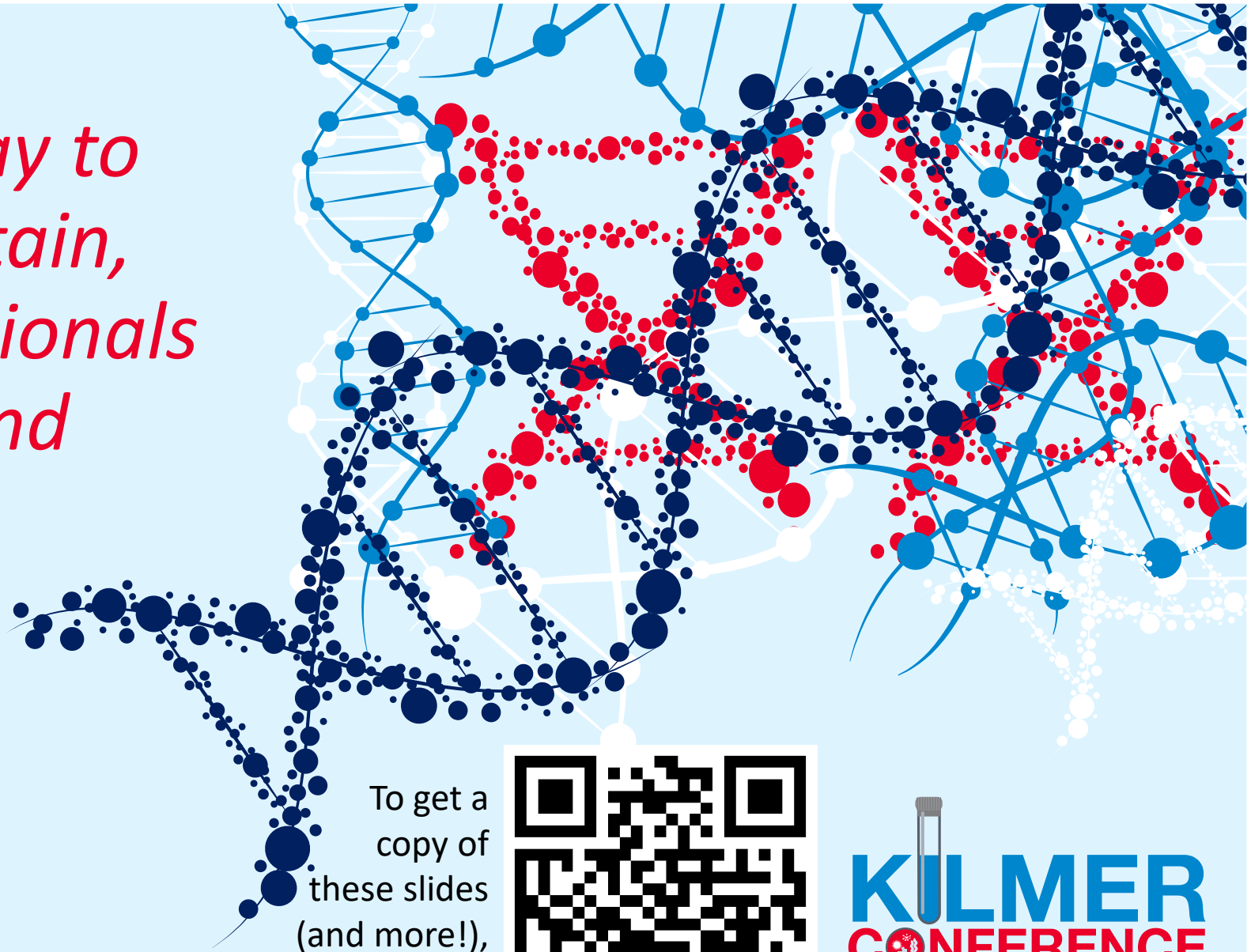

To get a copy of these slides (and more!), use this QR code!

https://sfsap.org/conference

KILMER CONFERENCE 2022

What is SfSAP?

Society for Sterility Assurance Professionals (SfSAP)

SfSAP has been established as a collaborative not-for-profit initiative by iia, AAMI, ASTM and PDA. It aims to enable the healthcare industry to:

- Collaborate and formulate a standard approach to meeting regulatory requirements related to the **competency** of those involved in the field of Sterility
- Create frameworks that can be used as a career development pathway, that will enable the sterilization community to **attract and retain** sterility assurance professionals throughout their sterility assurance career.
- Assist education delivery organisations in refining and maintaining content that supports the **development** of individuals in order to demonstrate "competency" as a sterility assurance professional.

SfSAP Working Groups integration with MDSAP defined competencies

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MDSAP Defined Competencies	SfSAP Working Groups
Microbiology	Industrial Microbiology & Microbial Controls WG
Packaging and Sterile Barrier Systems	**Packaging and Sterile Barrier System WG**
Environmental and Contamination Control	Industrial Microbiology & Microbial Controls WG Aseptic processing WG
Routine (Terminal) Sterilization	Radiation WG Terminal Sterilization Gas & Heat WG (EO and Moist Heat Subgroups)

- SfSAP Working Groups are aligned with the **Medical Device Single Audit Program** (MDSAP) Defined competencies
- The regulatory requirements are being addressed via the various working groups
- 6 WG consist of 55 people who represent 30 different healthcare companies.

Supportive Slide

Competencies of auditors as defined by MDSAP G0002.1004 Companion Document_rev 2017-04-13

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It is up to the Auditing Organization to determine the competencies required to achieve the audit objectives and to assign a competent audit team. However, the AO should identify auditors and/or technical experts having the competencies identified below.

The auditing of activities and processes contributing to the sterility of a medical device may involve the following competencies:

- **Microbiology:** Ability to assess the validation of sterilization processes and methods regardless of the availability of an established standard (or the lack of such a standard). Ability to assess the validation of environmental and microbial contamination controls. Ability to assess the validation of packaging activities and sterile barrier systems. A person deemed to have this competency would likely be educated as a medical microbiologist.
- **Packaging and Sterile Barrier Systems:** Ability to assess the validation of activities and processes for packaging and sterile barrier systems.
- **Environmental and Contamination Control:** Ability to evaluate the adequacy of environmental and microbial contamination control programs.
- **Routine Sterilization:** Ability to assess the validation of sterilization processes and methods where an existing established standard on the method exists other than aseptic processes. Ability to verify the implementation of non-standard sterilization activities and processes previously audited by someone having the microbiology competency. Ability to assess the implementation of activities and processes for packaging and sterile barrier systems previously audited by someone having the packaging and sterile barrier systems or microbiology competency. Ability to assess the implementation of environmental and microbial control activities previously assessed by someone having the microbiology or environmental and contamination control competency.

An auditor may possess several of these competencies

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How do we support healthcare quality management requirements?

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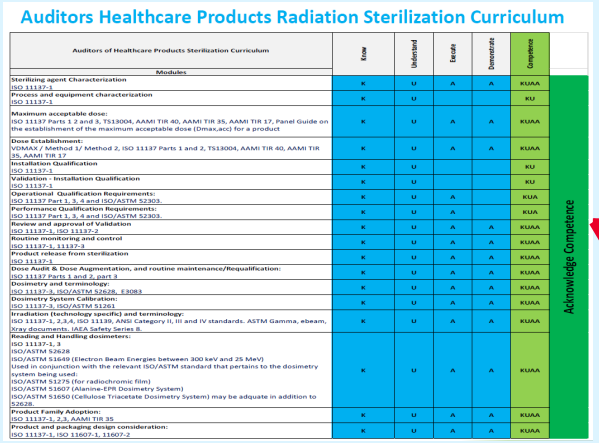
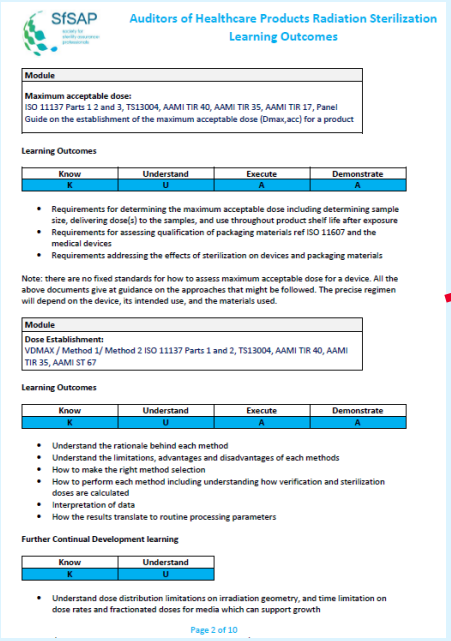


Auditors Healthcare Products Radiation Sterilization Curriculum

Auditors of Healthcare Products Sterilization Curriculum Modules	Know	Understand	Execute	Demonstrate	Competence
Sterilizing agent Characterization ISO 11137-1	K	U	A	A	KUAA
Process and equipment characterization ISO 11137-1	K	U			KU
Maximum acceptable dose: ISO 11137 Parts 1 2 and 3, TS13004, AAMI TIR 40, AAMI TIR 35, AAMI TIR 17, Panel Guide on the establishment of the maximum acceptable dose (Dmax,acc) for a product	K	U	A	A	KUAA
Dose Establishment: VDMAX / Method 1/ Method 2, ISO 11137 Parts 1 and 2, TS13004, AAMI TIR 40, AAMI TIR 35, AAMI TIR 17	K	U	A	A	KUAA
Installation Qualification ISO 11137-1	K	U			KU
Validation - Installation Qualification ISO 11137-1	K	U			KU
Operational Qualification Requirements: ISO 11137 Part 1, 3, 4 and ISO/ASTM 52303.	K	U	A		KUA
Performance Qualification Requirements: ISO 11137 Part 1, 3, 4 and ISO/ASTM 52303.	K	U	A		KUA
Review and approval of Validation ISO 11137-1, ISO 11137-2	K	U	A	A	KUAA
Routine monitoring and control ISO 11137-1, 11137-3	K	U	A	A	KUAA
Product release from sterilization ISO 11137-1	K	U	A	A	KUAA
Dose Audit & Dose Augmentation, and routine maintenance/Requalification: ISO 11137 Parts 1 and 2, part 3	K	U	A	A	KUAA
Dosimetry and terminology: ISO 11137-3, ISO/ASTM 52628, E3083	K	U	A	A	KUAA
Dosimetry System Calibration: ISO 11137-3, ISO/ASTM 51261	K	U	A	A	KUAA
Irradiation (technology specific) and terminology: ISO 11137-1, 2,3,4, ISO 11139, ANSI Category II, III and IV standards. ASTM Gamma, ebeam, Xray documents. IAEA Safety Series 8.	K	U	A	A	KUAA
Reading and Handling dosimeters: ISO 11137-1, 3 ISO/ASTM 52628 ISO/ASTM 51649 (Electron Beam Energies between 300 keV and 25 MeV) Used in conjunction with the relevant ISO/ASTM standard that pertains to the dosimetry system being used: ISO/ASTM 51275 (for radiochromic film) ISO/ASTM 51607 (Alanine-EPR Dosimetry System) ISO/ASTM 51650 (Cellulose Triacetate Dosimetry System) may be adquate in addition to 52628.	K	U	A	A	KUAA
Product Family Adoption: ISO 11137-1, 2,3, AAMI TIR 35	K	U	A	A	KUAA
Product and packaging design consideration: ISO 11137-1, ISO 11607-1, 11607-2	K	U	A	A	KUAA

Acknowledge Competence



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Auditors of Healthcare Products Radiation Sterilization Learning Outcomes

Module

Maximum acceptable dose:
ISO 11137 Parts 1 2 and 3, TS13004, AAMI TIR 40, AAMI TIR 35, AAMI TIR 17, Panel Guide on the establishment of the maximum acceptable dose (Dmax,acc) for a product

Learning Outcomes

Know	Understand	Execute	Demonstrate
K	U	A	A

- Requirements for determining the maximum acceptable dose including determining sample size, delivering dose(s) to the samples, and use throughout product shelf life after exposure
- Requirements for assessing qualification of packaging materials ref ISO 11607 and the medical devices
- Requirements addressing the effects of sterilization on devices and packaging materials

Note: there are no fixed standards for how to assess maximum acceptable dose for a device. All the above documents give at guidance on the approaches that might be followed. The precise regimen will depend on the device, its intended use, and the materials used.

Module

Dose Establishment:
VDMAX / Method 1/ Method 2 ISO 11137 Parts 1 and 2, TS13004, AAMI TIR 40, AAMI TIR 35, AAMI ST 67

Learning Outcomes

Know	Understand	Execute	Demonstrate
K	U	A	A

- Understand the rationale behind each method
- Understand the limitations, advantages and disadvantages of each methods
- How to make the right method selection
- How to perform each method including understanding how verification and sterilization doses are calculated
- Interpretation of data
- How the results translate to routine processing parameters

Further Continual Development learning

Know	Understand
K	U

- Understand dose distribution limitations on irradiation geometry, and time limitation on dose rates and fractionated doses for media which can support growth

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Supportive Slide

ISO 13485:2016 Clause 6.2
Requirements to be met by Medical Device Manufacturers

6.2 Human resources

Personnel performing work affecting product quality **shall be competent on the basis of appropriate education, training, skills and experience**.

The organization shall document the process(es) for **establishing competence, providing needed training, and ensuring awareness of personnel**.

The organization shall:

a) determine the necessary competence for personnel performing work affecting product quality;

b) **provide training** or take other **actions to achieve or maintain the necessary competence**;

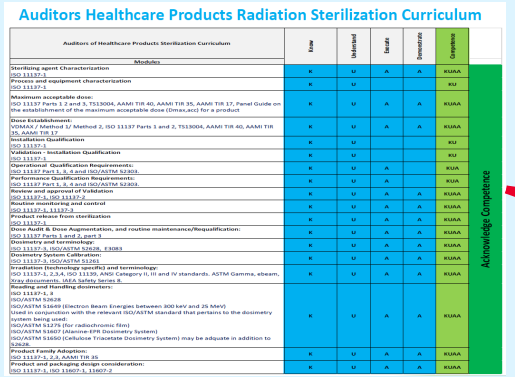
c) evaluate the effectiveness of the actions taken;

d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives;

e) maintain appropriate **records of education, training, skills and experience** (see 4.2.5).

The SfSAP Learning Framework and Learning Outcomes addresses the requirements for there to be documented evidence of competency and defined in ISO 13485:2016, Clause 6.2 Requirements to be met by Medical Device Manufacturers.

How do we support EU Medical Device Regulations?



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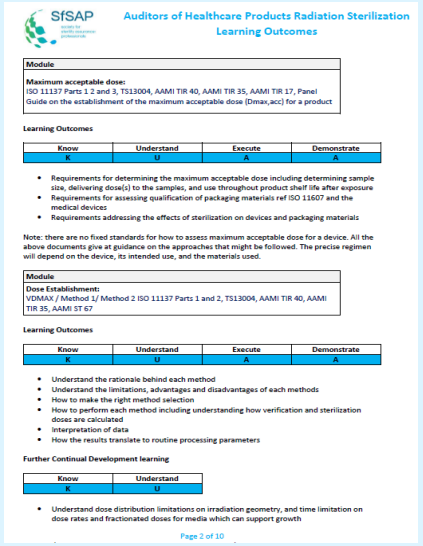

SfSAP

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MDR Annex VII
Requirements to be met by Notified Bodies

3. Resources
3.2 Qualification criteria in relation to personnel
3.2. 1 The **Notified Body shall establish and document qualification criteria** and procedures for selection and authorization of persons involved in conformity assessment activities, including as regards **knowledge, experience and other competency** required and the required initial and ongoing training. The qualification criteria **shall address the various areas** within the conformity assessment process, such as **auditing, product evaluation or testing, technical documentation review and decision making**, as well as devices, technologies and areas, such as biocompatibility, **sterilisation**, tissues and cells of human and animal origin and clinical evaluation, covered by the scope of designation.

The SfSAP Learning Framework and Learning Outcomes addresses the requirements for there to be documented evidence of competency and defined in the MDR.

Supportive Slide

Why have formalized curricula?

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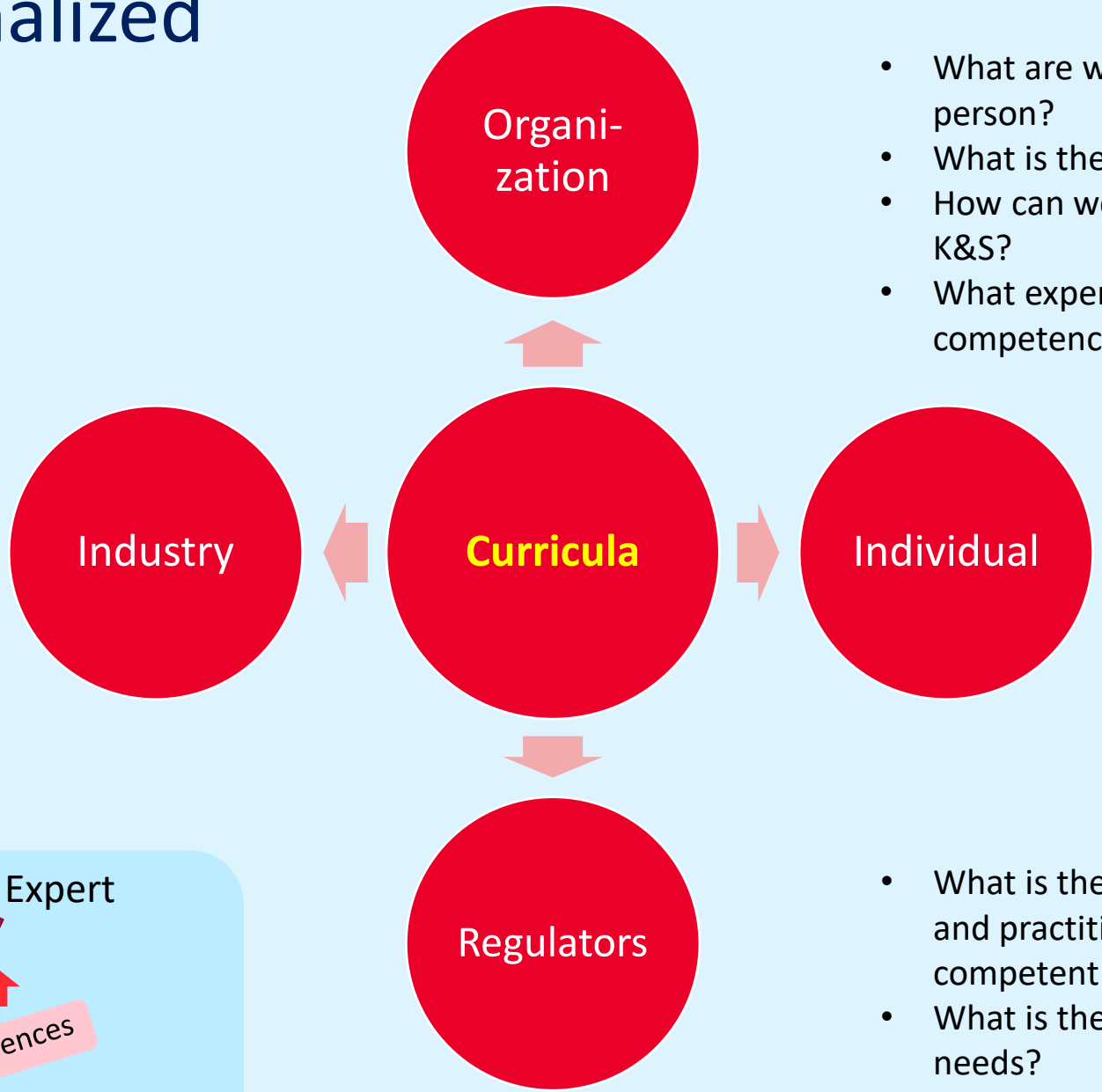


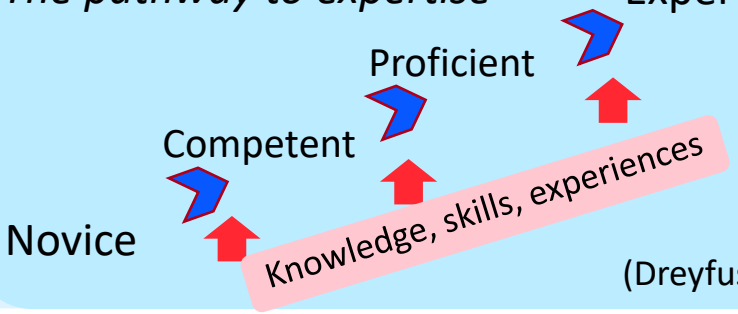
- What are we looking for when hiring a new person?
- What is the collective set of K&S we need?
- How can we help our people grow their K&S?
- What experiences will shape one's competence?

- How can we **attract** new talent?
- How can we **develop** professionals that will be critical to the future of our industry and our patients?
- How can we **retain** professionals who will become industry experts?

- If I want to become an expert in this field, what's my path?
- How can I do this in a step-wise manner?

- What is the set of K&S that industry experts and practitioners say are need to be competent as an expert?
- What is the collective set of skills a firm needs?
- What is the set of education, training, and experiences an expert should have?

The pathway to expertise



(Dreyfus Model)

Why is this needed now?

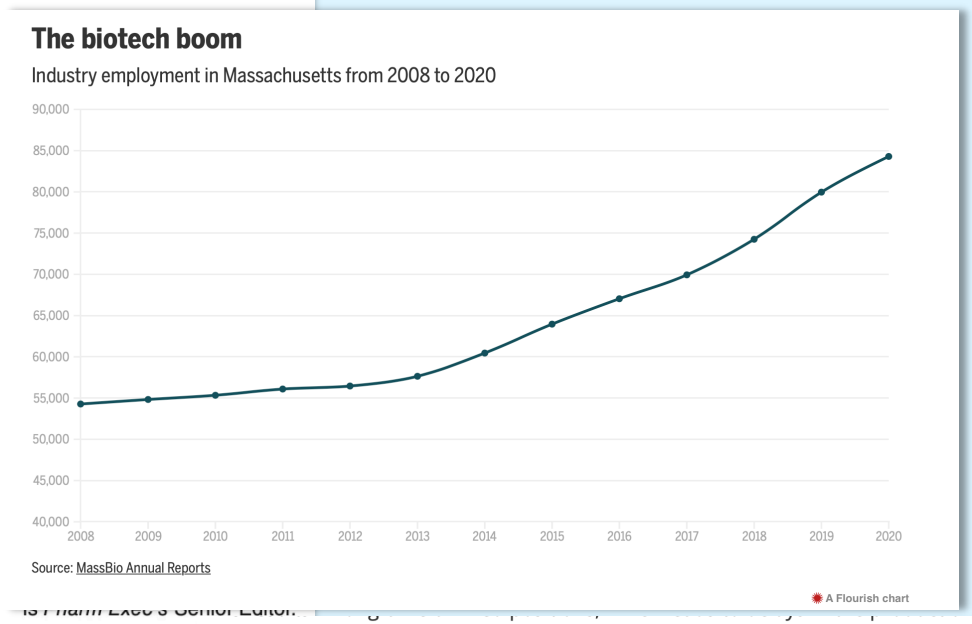
More Jobs and Less Talent Has Created an Imbalance in Pharma

September 14, 2021
Elaine Quilici
Pharmaceutical Executive, Pharmaceutical Executive-09-01-2021, Volume 41, Issue 9

If not addressed, effects could impact innovation, diversity.

Over the past year, there has been an upheaval in human resources throughout the biopharma industry. An explosion of new biotechs and positions has created a shortage of talent—especially technical workers.

According to a recent talent trends survey by Randstad Sourceright, 75% of life sciences



FIERCE Pharma

Manufacturing Marketing Pharma Vaccines Trending Topics Special Reports

MANUFACTURING

Pfizer, Moderna and Alnylam flag pharma labor shortage in Massachusetts—and the people bottleneck doesn't stop there

By **Fraiser Kansteiner** · Aug 3, 2021 01:36pm

Moreover, if companies end up hiring under-qualified people for the job, they will have to spend money and time to train them, which also slows the adoption of new technologies.

According to the 2019 annual economic survey by Eurochambres, a representative of the business communities in Europe, the lack of skilled workers is one of the biggest challenges faced by European companies.

All this has a wider economic impact. According to the OECD, countries with labour market imbalances also show lower productivity levels.

Addressing the Tripartite Social Summit in October last year, Eurochambres President Christoph Leitl warned: "We are sleep-walking into a highly damaging socio-economic crisis by failing to address growing skills mismatches across much of the EU."

Supportive Slide

From novice to expert – the Dreyfus Model

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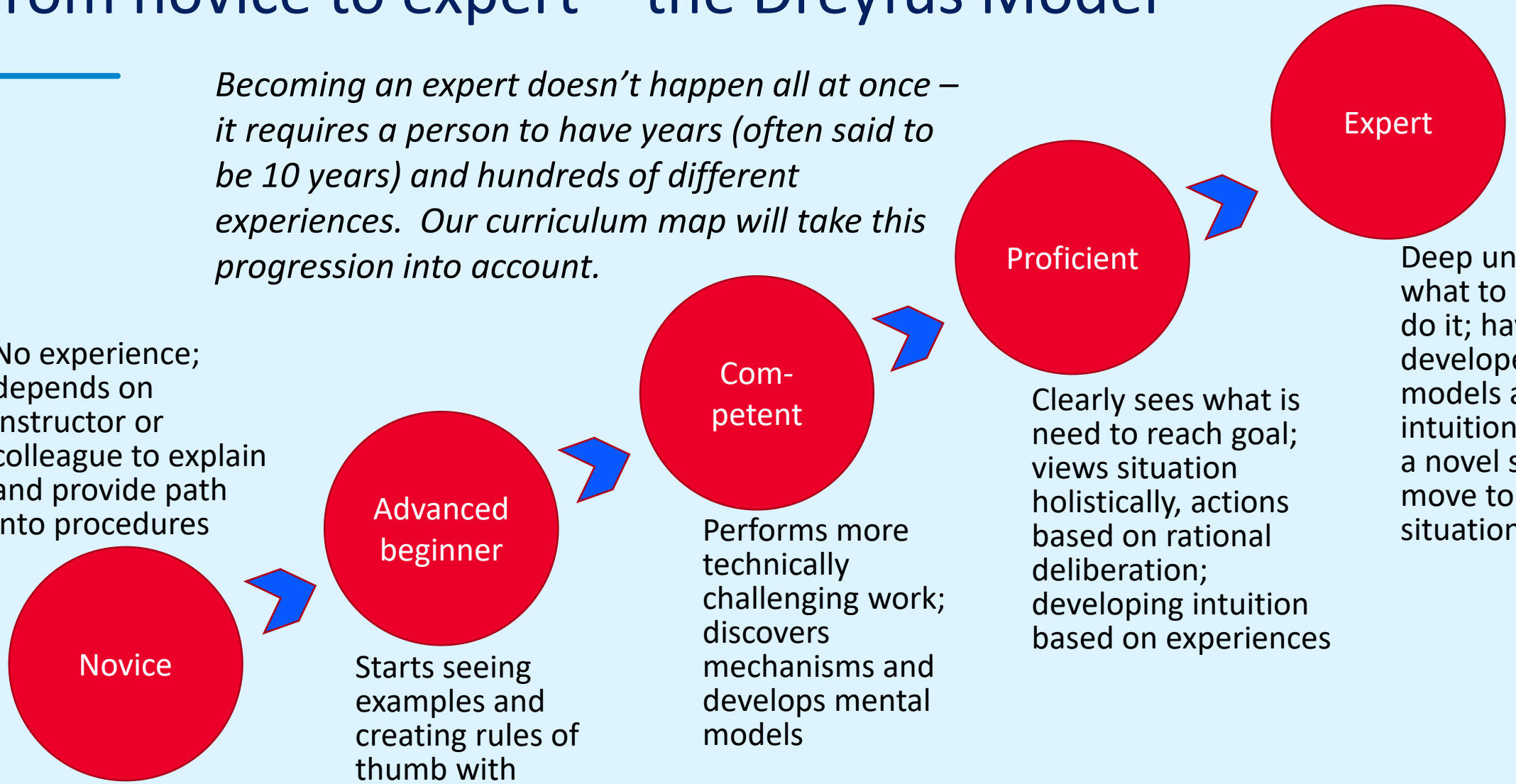
Becoming an expert doesn't happen all at once – it requires a person to have years (often said to be 10 years) and hundreds of different experiences. Our curriculum map will take this progression into account.



Supportive Slide

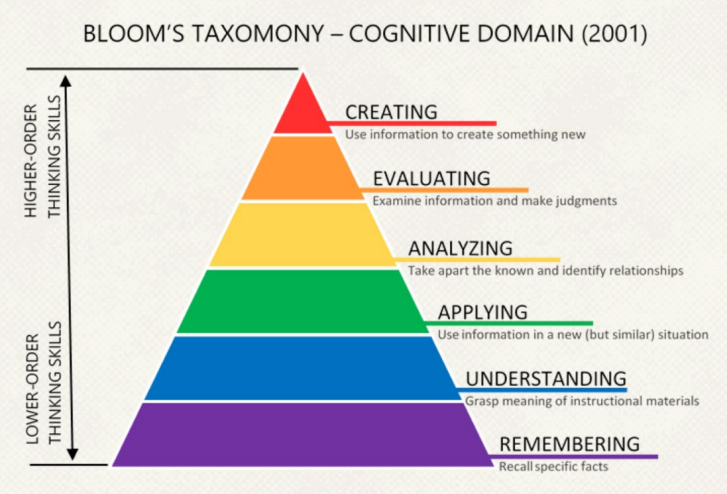
Develop: What contributes to developing expertise

KNOW
What are the topics in this module that one needs to KNOW about?

APPLY
How does an expert use (APPLY) this knowledge in their work?

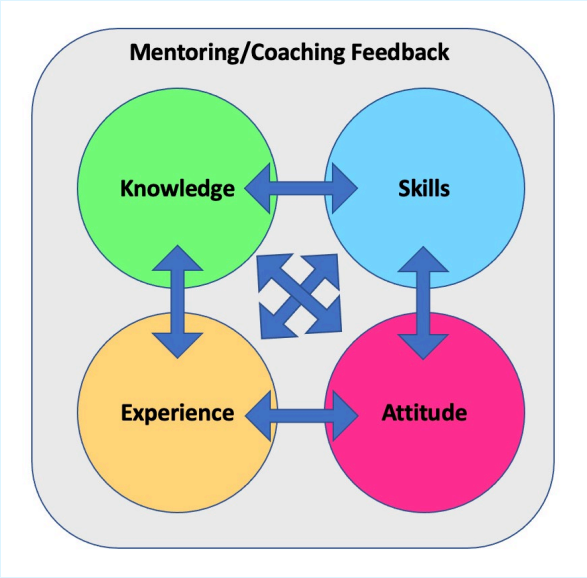
EXECUTE
What experiences should a developing expert have where they can apply this knowledge?

DEMONSTRATE
How does a learner demonstrate to an incumbent expert or authority that the learner has the relevant knowledge and skills?

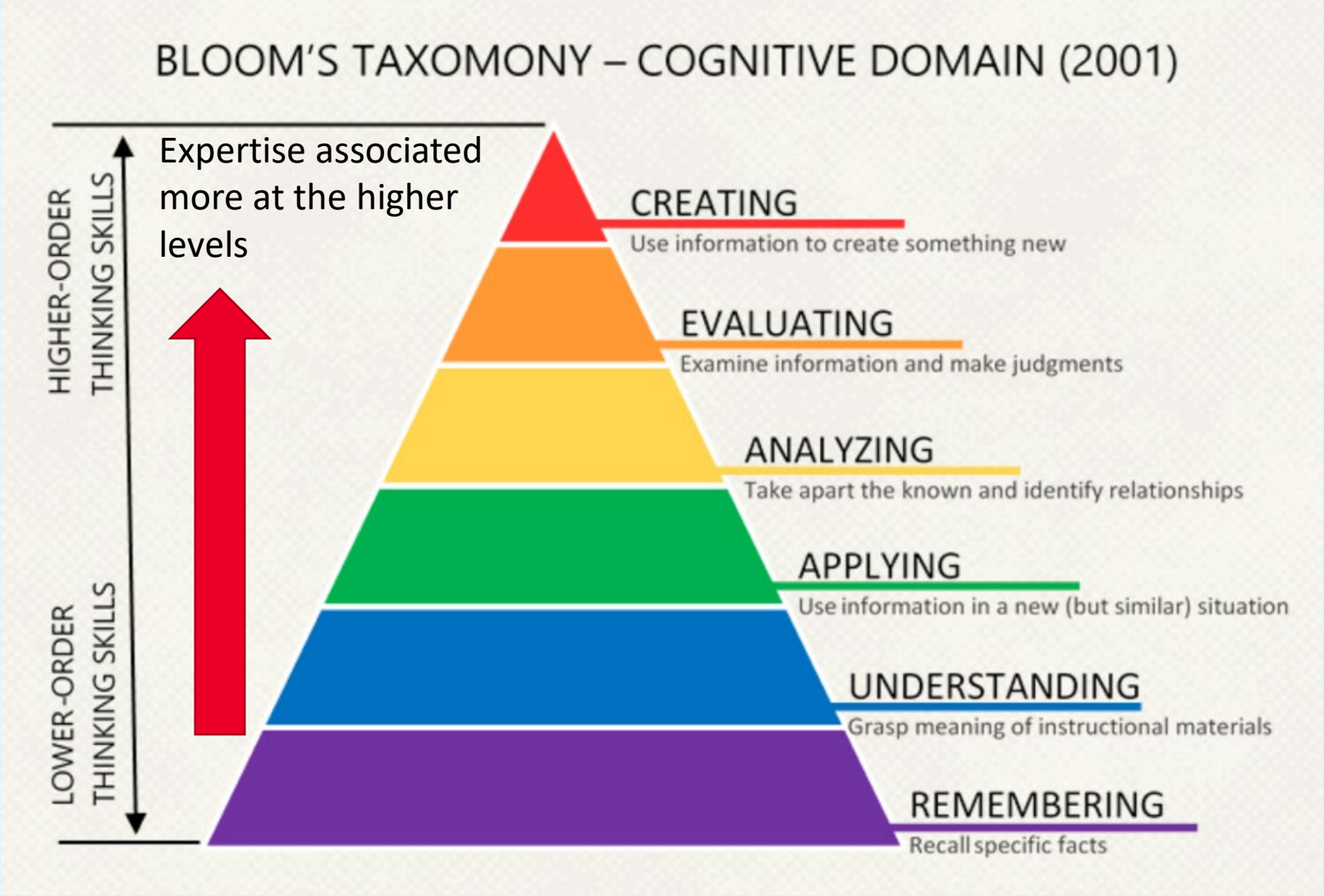


Using the Learning Frameworks and Learning Outcomes to support Education Delivery Organisations (EDO) develop training which is in line with the needs of the industry, and support the planning and advancement of sterilization professionals in their careers

Aseptic Processing Learning Framework Module / relevant topics	Relevant regulations, standards, tech reports	KNOW – What are the topics in this module that I need to know about?	APPLY – How does an expert use (apply) this knowledge?	EXECUTE – What experiences should I have where I can apply this knowledge?	DEMONSTRATE – How can I demonstrate to an incumbent expert that I have the relevant knowledge and skills?	Competence
(Added detail)		Add more detail here about what is included in the relevant topics covered for a specific role (e.g, QA, ops, MSAT) if desired	Statements would start with a behavioral verb linked to learning objectives covered for a specific role (e.g, QA, ops, MSAT) if desired	Specific examples of experiences could be listed for a specific role (e.g, QA, ops, MSAT) if desired	What actions and degrees of performance would be looked for by an expert; links learning objectives identified in "APPLY" column for a specific role (e.g, QA, ops, MSAT) if desired	
Microbiology: Environmental Monitoring (focus on the EM program) Techniques, Guidance requirements, Risk-based location selection						
Microbiology: Basic Identification and classification Types of microbes, Spores vs Non-Spores Organisms, Sources and life cycles of micro organisms; practical differences between various methods to identify micro organisms; current regulatory expectations and industry practices on how micro laboratories can support AP manufacturing.						
Quality Systems: Quality Risk Management (QRM) Applying QRM to aseptic processing (AP); potential hazards and vulnerabilities in AP; current regulatory expectations and industry practices.						
Quality Systems: Regulatory/GMP expectations that apply to AP Current and relevant health authority (regulatory) and compendial requirements and regulatory expectations; current industry thinking, options, and practices (good and bad) related to aseptic processing that have been seen during inspections.						
Quality Systems: Qualification and validation (not including aseptic processing simulations) How qualification and validation apply in an AP setting; current regulatory expectations and industry practices.						
Quality Systems: Deviation management, investigations, CAPA, change control Quality management systems (QMS) programs and processing systems and how they AP and sterility assurance; tools/methods used in performing root cause analysis of contamination issues; current regulatory expectations and industry practices.						



Developing thinking (cognitive) skills



For example:

I can create a validation protocol that is technically correct and meets regulatory expectations.

I can evaluate an operational procedure to determine if it is technically correct.

I can analyze a failure and provide ideas on what might have gone wrong.

I can apply my understanding in preparing a loading configuration for new equipment.

I understand **why** the loading configuration is important to achieving sterility.

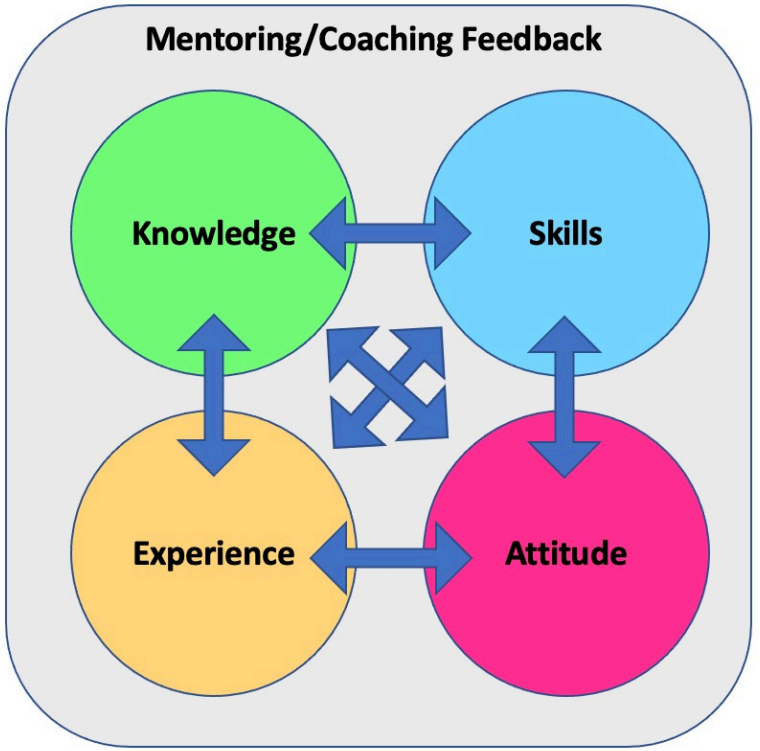
I remember **how** to correctly load the autoclave.

Supportive Slide

How one develops expertise, 1

- **Knowledge**. This involves having the foundational knowledge and understanding the principles involved with microbial contamination and ways to prevent it. This knowledge is the basis for actions and decisions. Subject matter experts who developed the curriculum have identified topics and subtopics of knowledge that a sterility professional in a particular role should have.

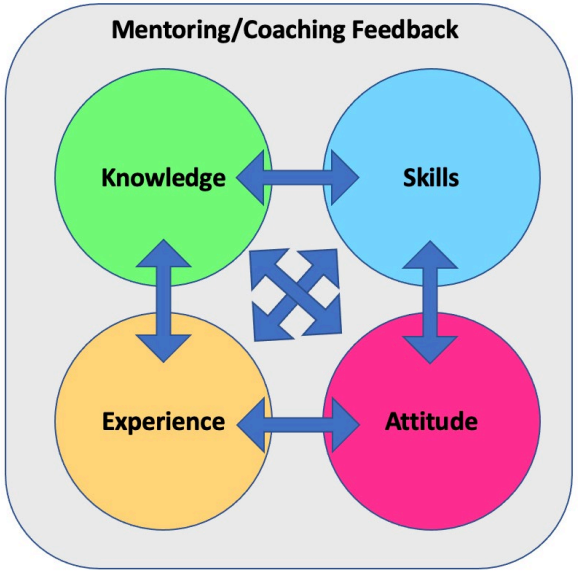
- **Skills**. Skills include thinking or "cognitive" skills that are used in many different ways – making decisions, considering risks, evaluating situations, analysing new problems, and developing plans and protocols. The subject matter experts who developed the curriculum have identified certain skills that a sterility professional in a particular role should be able to demonstrate.



Supportive Slide

How one develops expertise

- **Attitude**. While harder to teach, attitudes are usually observed and absorbed by someone in a given line of work so that they are effective in what they do. This is the professionalism one needs – for example, being prepared, not taking shortcuts, being concerned for the patient, being diligent, and not giving up too soon.
- **Experience**. A characteristic of an expert is that they have had a variety or repertoire of experiences that they can draw on – the more you do, the better you get. The opportunity that you (and your management) have is finding opportunities where you can apply – and expand – your knowledge and skills through different experiences.
- **Feedback from mentors and coaches**. One of the most important factors in becoming an expert is having people who will provide feedback – helping you stay on the correct course or giving you constructive criticism that helps you understand where you may have been off track. You might have different mentors or coaches for different facets of your work; they could be supervisors or colleagues that are more knowledgeable than you are in each aspect of sterility assurance.



Supportive Slide

Retain: A range of possibilities being considered

Qualify

- Person has met requirements allowing them to adequately perform role
- *Qualified to work in an aseptic processing area, qualified to use a laboratory instrument*

License

- Person has been given permission by a governmental body to perform defined actions
- *Driver's license, medical license*

Certify

- Person has been confirmed that they initially and continue to meet the standards set by a body of recognized professionals, experts
- *Certified public account, certified by a board of medical practice*

Give those sterility assurance professionals industry recognised credentials.

Supportive Slide

Develop: One idea – document knowledge, skill, experience: **Portfolios**

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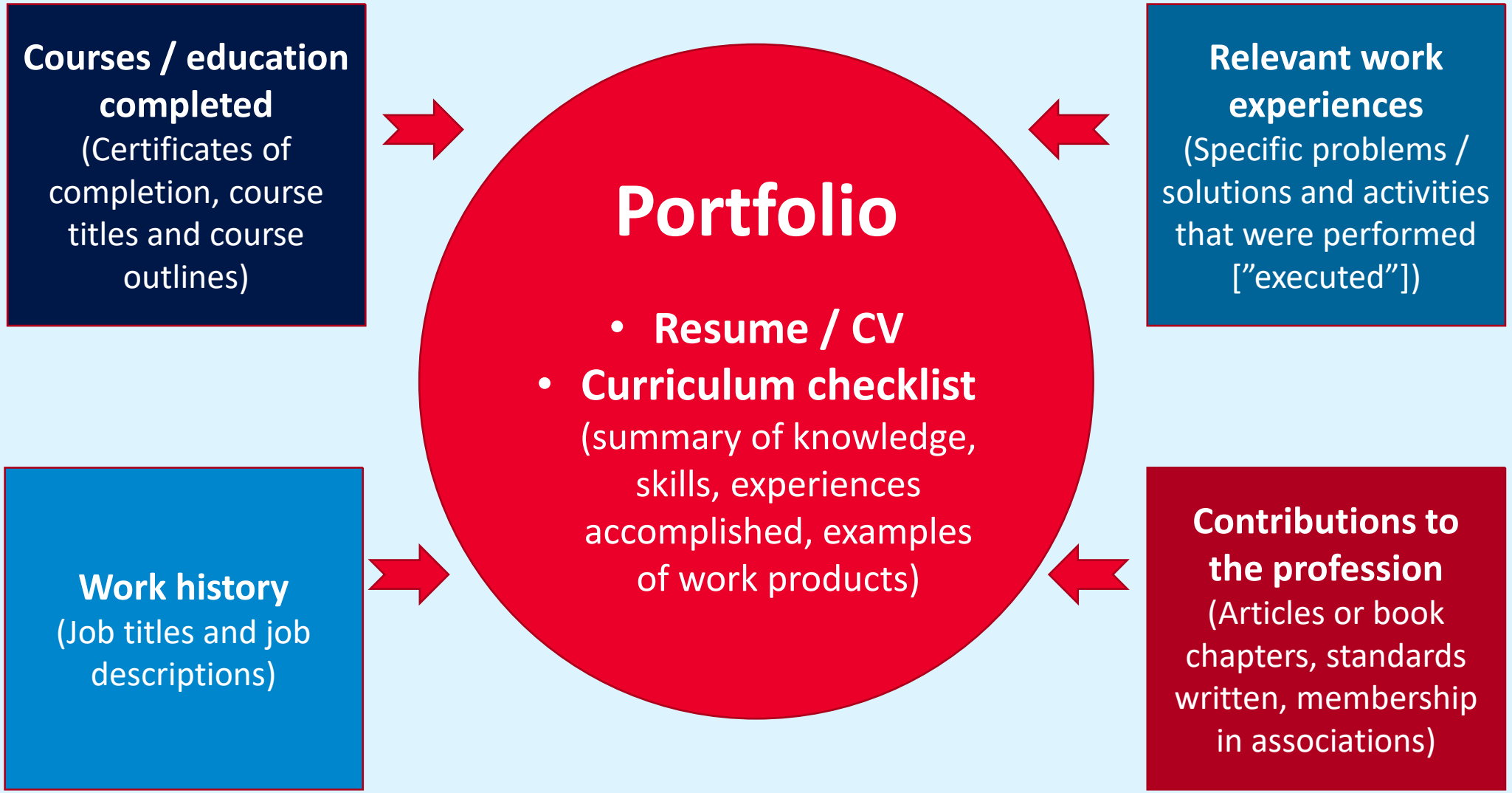

Supportive Slide

Acknowledged Competency

Global industry experts identify knowledge and skills needed by experts in that field

Know

What are the topics in this module that an expert in this domain needs to know and understand about?

- **Build foundation of knowledge in scientific area associated with the sterilization modality**
- **Network with experience users of the science associated with the sterilization modality**

Apply

How does an expert use (apply) this knowledge?

- **Can vary based on the role of the person (e.g., QA, engineering, MSAT)**
- **Statements begin with a behavior verb (e.g., 'discuss', 'assess') that can become a learning objective**

Demonstrate

How can someone demonstrate to an incumbent expert or authority that they have the relevant knowledge and skills?

- **This is intended to provide confidence to an organization, regulatory authority, colleagues and the individual that they have the needed knowledge and skills to be successful in the specific field of interest.**

Execute

What are specific examples of experiences could be listed whereby someone develops a "repertoire of experiences"?

- **Could include short- or long-term projects, work experiences, product types**
- **For example, "Uses risk assessment to define an environmental monitoring (EM) program."**

- *Knowledge* and skill learning opportunities can come from a variety of sources
- *Applying* can depend on the role the indivual has
- *Execution* emphasises the practical nature of learning
- *Demonstration* may be to a variety of knowledgable persons

Supportive Slide

Link Framework to Outcomes

Healthcare Products Radiation Sterilization Learning Framework Module	Know What are the topics in this module that I need to know and understand about?	Apply How does an expert use (apply) this knowledge?	Execute What experiences should I have where I can apply this knowledge? (Learn by doing; developing a repertoire of experiences)	Demonstrate How can I demonstrate to an incumbant expert that I have the relevant knowledge and skills?	Competence	Acknowledge Competence
Maximum acceptable dose: ISO 11137 Parts 1, 2 and 3, TS13004, AAMI TIR 17, Panel Guide on the establishment of the maximum acceptable dose (Dmax, acc) for a product						
Dose Establishment: VDMAX 15 & 25 / Method 1/ Method 2 ISO 11137 Parts 1 and 2, TS13004, AAMI TIR 40, AAMI TIR 35, AAMI ST67						
Performance Qualification Requirements: ISO 11137 Part 1, 3, 4 and ISO/ASTM 52303						
Operational Qualification Requirements: ISO 11137 Part 1, 3, 4 and ISO/ASTM 52303.						
Dose Audit & Dose Augmentation, and routine maintenance/Requalification: ISO 11137 Parts 1 and 2, part 4						
Dosimetry and terminology: ISO/ASTM 52628, E3083						
Dosimetry System Calibration: ISO/ASTM 51261, ISO/ASTM 51707						
Irradiation (technology specific) and terminology: ANSI Category II, III and IV standards. ASTM Gamma, ebeam, Xray documents. IAEA Safety Series 8.						
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Product Family Adoption: AAMI TIR 35						

Module
Performance Qualification Requirements: ISO 11137 Part 1, 3, and 4, ISO/ASTM 51608, 51649, 51702, 52628 and 52303.

Learning Outcomes

- Know and understand the requirements of performance qualification for a product
- Know, understand, and demonstrate the interpretation of the standard requirements
- Know, understand, and demonstrate how to translate the standard requirements into your specific process requirements
- Know, understand, and demonstrate how the orientation or configuration on the impact of product fill
- Know, understand, and demonstrate how the elements that need to be covered during PQ
- Know, understand, and demonstrate how to select representative products/processing categories
- Know and understand the importance of traceability
- Know and understand the importance and impact of uncertainty
- Know, understand, and demonstrate how to create the mapping grid for your container and process
- Know and understand the considerations of centre plane mapping
- Know, understand, and demonstrate how to determine the type, number and spacing of dosimeters
- Know, understand, and demonstrate the analysis of results and comparison to previous data to assess the impact of the performance qualification

Learning Framework

This document contain the modules that are key to becoming competent in the specific modality. Each module has defined learning outcome that are contained in the Learning Outcomes document.

Learning Outcomes

This document contains the key learning objectives that you should achieve to demonstrate competency in that module.

Supportive Slide

Building your portfolio

Module
Performance Qualification Requirements: ISO 11137 Part 1, 3, and 4, ISO/ASTM 51608, 51649, 51702, 52628 and 52303.

Learning Outcomes

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Synergy Health Plc **March 2013 to September 2013**
UK and Ireland Radiation Technical Manager

- Responsible for giving guidance to all the group wide quality mangers in all matters relating to irradiation and compliance to the requirements of ISO 9001, 11137, 13485, FDA, JPAL, (MHRA where relevant).
- Ensuring that sites have pFMEAs and perform OQ in line with the requirements of ISO11137 and local site procedures. Being the key contact for key customers, giving them advice and training on their responsibilities in meeting the requirements 11137 Part 1 and 2 and changes in FDA rules relating to the sterilization industry and the implications it would have on customer submissions.
- Perform audits to ensure that all sterilization sites are compliant to ISO 9001, 11137, 13485, FDA, JPAL. Providing training workshops through PHSS (Pharmaceutical and Healthcare Services Society), ASTM Workshops and other industry recognized organizations in the requirements of ISO11137 part 1.
- Global Programme Validation Manager for IFS (Enterprise Resource Planning) System.
  Software was Implemented in 91 locations in 15 countries.
  Part of the leadership team that wrote the URS.
  Audited potential software Suppliers before submission of RFI (Request For Information).
  Performed the validation using the software V model, blackbox testing, IQ, OQ, PQ at a global and local site level.
  This included the validation of the software ensuring compliance to FDA 21 CFR 11.
- Ensuring that the business and region remains up to date in the development of standards within the relevant ISO, ASTM committees with respect to irradiation and medical device sterilization.
- Using Statistical Process Control data such as Cp, CpK, PpK, UCL, LCL, Histograms to monitor the performance and capability of Gamma, E-Beam and Ethelyne Oxide processes to ensure that they were in control.
- Performing risk based assessments on the processing and release of product using the guidance in ISO 14971.

Synergy Health Plc. **June 2010 – March 2013**
UK Quality Manager Applied Sterilization Technologies

- As Quality Manager for the UK I had ultimate responsibility for ensuring that all 8 sterilization sites and 2 laboratories are compliant to ISO 9001, 11137, 13485, FDA, JPAL, MHRA regulatory requirements.
- Providing guidance to the local site Quality Managers when problem solving and ensuring that thorough root cause investigation, analysis, reporting of CAPA was performed.
- Facilitated Quality Circles at a local site level, to ensure that all of the local site management team were involved in continuous quality improvement.
- Having trained as a lead auditor, I am part of the corporate auditing team and perform audits of the Synergy Health Group suppliers and sterilization sites across the world.
- Ensuring the quality department managers continue to be trained and were up to date with the latest developments in the ISO standards relating to our field.
- As part of the senior AST UK management team, had to ensure that all quality matters are communicated at the highest level.

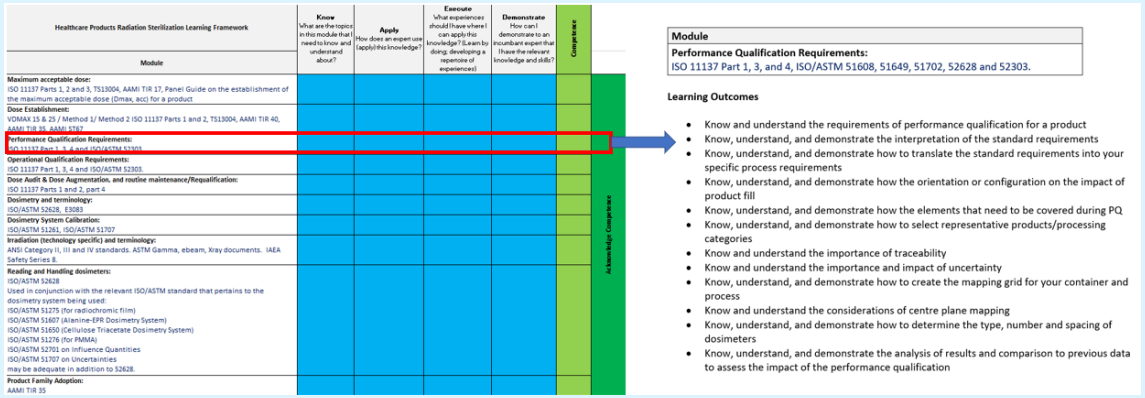
Isotron **May 2006 - June 2010**
UK Quality Engineer

- This role involved supporting the UK Quality Manager and site Quality Managers in customer, FDA, MHRA and Regulatory Body audits.
- Was the main contact for key customers giving them support and advice on their responsibilities in meeting the requirements 11137 Part 1 and 2.
- Having trained as a lead auditor, performed Internal audits at various sites across the world to ensure that they were compliant to the regulatory requirements of ISO 9001, 11137,13485, FDA, JPAL, (MHRA where relevant) and compliance to the QMS.
- Instrumental in writing and implementing the CAPA database, ASTM PQ templates and the dosimeter calibration function for the entire Isotron group

Build your portfolio of competency. Certificates from training, experience gained from work documented in your CV etc

Supportive Slide

Attract: Create, plan and evaluate pompetency



Healthcare Products Radiation Sterilization Learning Framework Module	Know What are the topics in this module that I need to know and understand about?	Apply How does an expert use (apply) this knowledge?	Execute What experiences should I have where I can apply this knowledge? (Learn by doing; developing a repertoire of experiences)	Demonstrate How can I demonstrate to an incumbent expert that I have the relevant knowledge and skills?	Competence	Acknowledge Competence
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Product Family Adoption: AAMI TIR 35						

Module

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CERTIFICATE

ASTM International Subcommittee E10.01
Dosimetry for Radiation Processing
Certificate of Attendance
Arthur Dumba

Panel on Gamma and Electron Irradiation

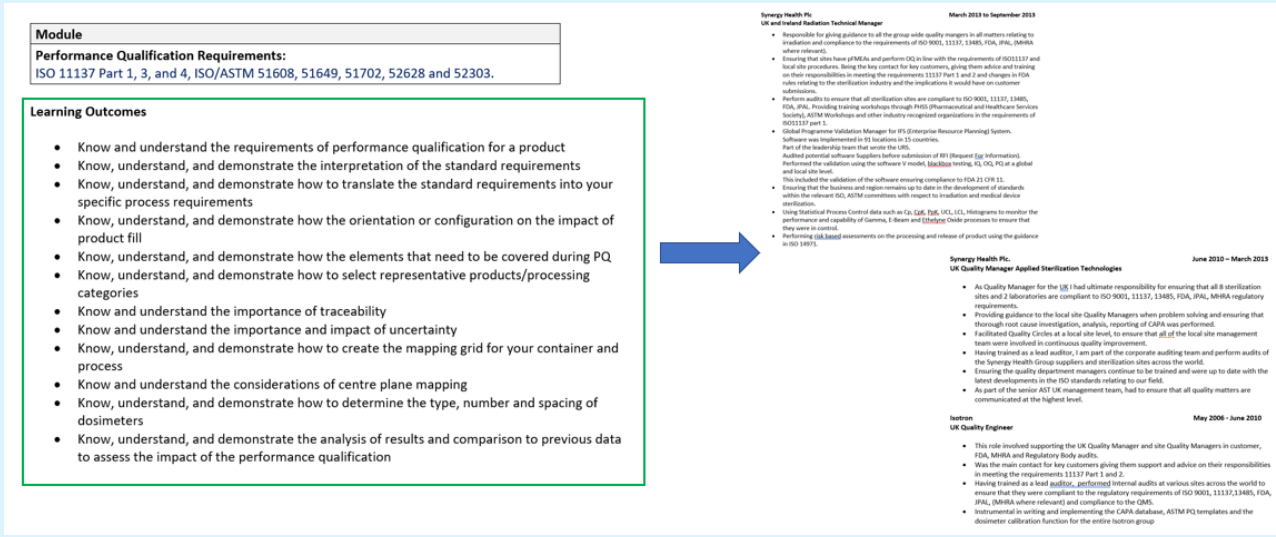
Radiation Sterilisation of Medical Devices - Implementation of EN/ISO 11137 Course held at Ramada Hotel, Solihull on 12 July 2007

Certificate of Attendance issued to
Arthur Dumba

John Harries
Panel on Gamma and Electron Irradiation

The frameworks support the healthcare sterilization industry in the following ways:

- Assists individuals to create, plan and advance their careers.
- Supports employers meet regulatory requirements by providing career development pathways for staff.
- Support regulators in helping them determine the elements of training required to meet competency as defined in the MDSAP.



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Synergy Health Plc — March 2013 to September 2013
UK and Ireland Radiation Technical Manager

Synergy Health Plc. — June 2010 – March 2013
UK Quality Manager Applied Sterilization Technologies

Isotron — May 2006 - June 2010
UK Quality Engineer

Competency assessment

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Product Family Adoption: AAMI TIR 35						

Once your portfolio for a specific module is complete with evidence you Know-Apply-Execute- and Demonstrate, you can show competency in that specific module

Supportive Slide

Individuals/organizations using the learning frameworks and learning outcomes

CONTINUITY FOSTERING OUR FUTURE

To support individuals and organisations in gaining the **appropriate education, training, skills and experience** the SfSAP has a Learning Outcomes Guide:

Individuals and Organizations

The SfSAP Curricula and learning outcomes can be use by individuals and organisations for the following:

- Develop training plans
- Determine training courses that should be attended
- Understand the Competency elements (**Know**, **Apply**, **Execute** and **Demonstrate)** that are required.
- Understand the learning outcomes required for courses attended or training taken.
- Monitor progress towards demonstrating competency.

Supportive Slide

Continuing our path forward

What SfSAP is working on:

- Refining learning frameworks and learning outcomes
- Identifying activities (e.g., auditing, designing facilities) that would then be mapped to items in the frameworks and outcomes
- Working with experts to identify key experiences important in developing expertise
- Categorizing framework items and outcomes that provide a three-level, step-wise approach for moving through the curriculum
- “Validating” competency curricula with experts
- Sharing the model and results with industry, regulators, and training / educational organizations

Supportive Slide

CONTINUITY FOSTERING OUR FUTURE

Try it!

https://sfsap.org/insight/

For an individual

Apply the framework and outcomes to a ***person*** in your organization. Where are they in their progress to being an expert? What are the gaps?

For your organization

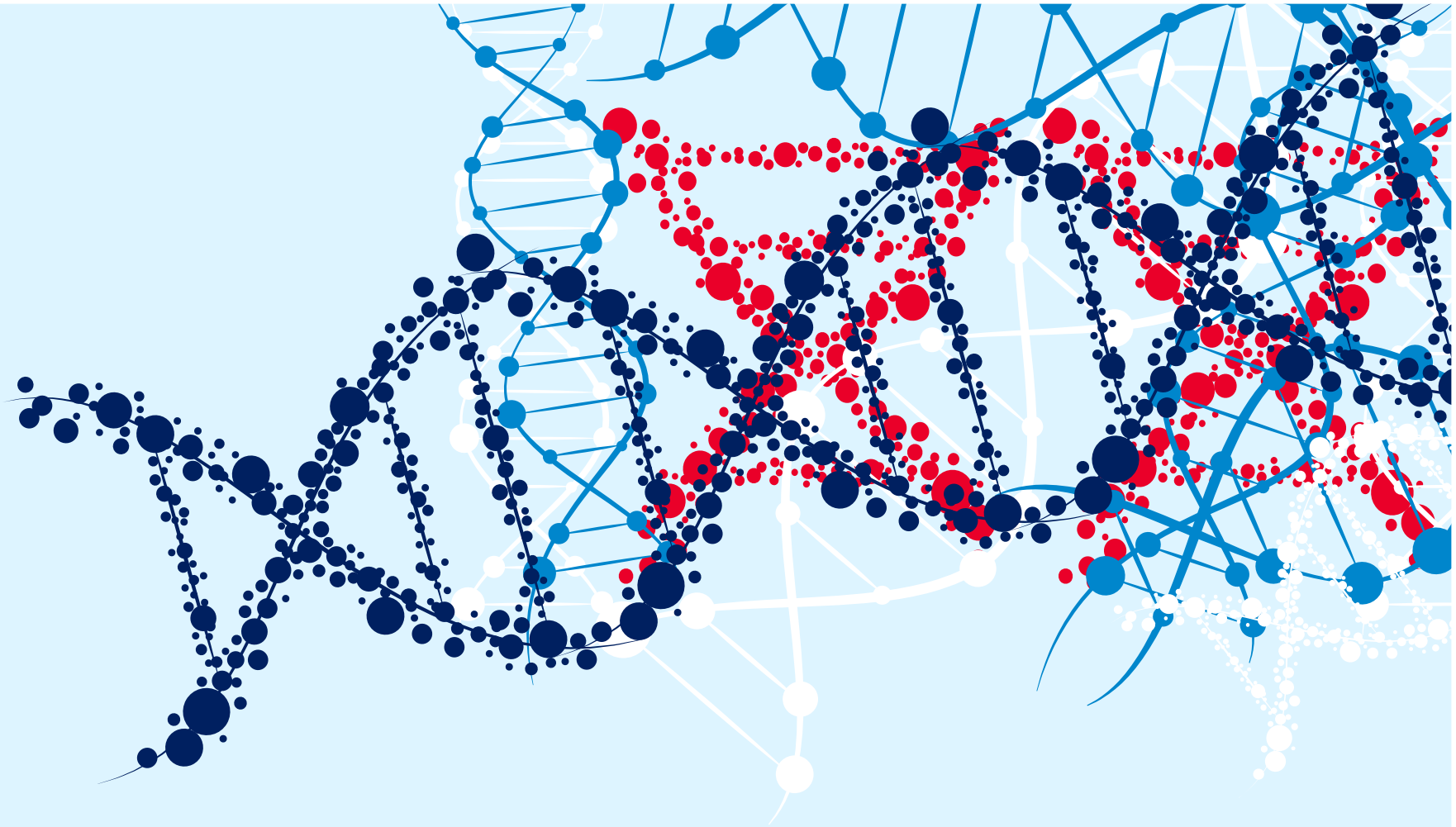
Apply the framework and outcomes to your ***organization***. Does your organization collectively have the expertise that it needs? What are the gaps?

Give us feedback!

Five simple questions

https://www.sfsap.org/survey/

1. Did you find the framework and outcomes useful?
2. How can it be improved?
3. What benefits would this provide individuals as they develop their knowledge and skills?
4. What benefits would it provide your organization?
5. Would you use it?



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CONTINUITY | FOSTERING OUR FUTURE