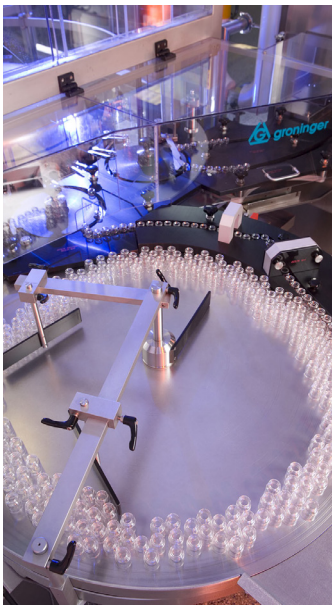
Annex 15 is Changing.
Are You Ready?

Now is the time to plan for the impact the revised Annex 15 will have on your company's qualification and validation strategy. IPS experts have first-hand intelligence on the proposed changes and have the knowledge, skill and passion required to guide you through this process.

The changes to Annex 15 are significant and represent an updated understanding of the lifecycle approach to qualification and validation by the EU in comparison to the original release in 2001. Various sections have been modified and added, resulting in a new framework that establishes process knowledge and risk assessment as the foundation for a successful qualification and validation effort. Companies should take the time now to strategically prepare for the release of this new edition and ask themselves - are we ready? If not, IPS is here to help you prepare.

Table of Contents Sample

2001 Version	2014 Version - Draft
Principle	Principle
Qualification and Validation	General
Planning for Validation	Organizing and Planning for Qualification & Validation
Documentation	Documentation including Validation Master Plans
Qualification	Qualification Stages for Facilities, and Equipment
Process Validation	Process Validation
Cleaning Validation	Verification of Transportation
Change Control	Validation of Packaging
Revalidation	Qualification of Utilities
Glossary	Validation of Test Methods
	Cleaning Validation
	Re-qualification
	Change Control
	Glossary



What is Changing and Why?

- Evolving to a science and risk-based approach with a clear influence from ICH Q8, Q9, Q10
- Starts with process knowledge and understanding
- Concise and thorough – covering entire commissioning, qualification and validation lifecycle
- Additional guidance on deviation and change management
- Instructions for qualification of 3rd party services
- Two different approaches to process validation – traditional and continuous process verification
  - Combination – hybrid approach
  - On-going process verification
  - 3 batches
- Cleaning validation – health based limits / toxicological data (PDE)

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Annex 15 is Changing.
You Need Experts.

Putting the time in now to understand the proposed changes will ensure a smooth transition when the guidance is updated.

Get Educated: Schedule a Consulting Meeting or a Lunch and Learn

IPS experts are available to discuss the impacts the updates could have on your facility and how to prepare. We can also host a training session at your site, at one of our office locations, or on-line to give you the information you need.

Make a Plan: Start the Conversation Internally

Now is the time to begin your preparations to review how your master plan, validation strategies and bottom line may be impacted. IPS can give you the tools and knowledge you need for a smooth and cost-effective transition.

Michael Westerman

Compliance Operations Director / Subject Matter Expert

Mr. Westerman has over 13 years of experience providing project management, equipment, software, and process validation, and quality / operational management in regulated industries. Industry experience is backed up with a strong educational background in biology, technical quality engineering and business that uniquely positions me to be successful in a wide variety of leadership roles in the biotech / pharma industry.

Mike is part of the PQLI working group with International Society of Pharmaceutical Engineers (ISPE) that has worked to consolidate ISPE's comments on the proposed revision.

Vince Cebular

Vice President of Compliance

Mr. Cebular has more than 20 years of experience in engineering and validation within the pharmaceutical and biotech industries. He has a broad range of experience in the areas of bulk drug manufacturing, aseptic processing and filling, solid dosage manufacturing and packaging, containment facilities, vivariums, utility systems, building automation systems, and laboratory support systems. He is experienced in the preparation and execution of master plans, commissioning forms, and protocols for many types of equipment, systems, and utilities. Vince is considered an SME in applying risk-based compliance strategies that align with the revised Annex 15 requirements.

Mark Rezac, PE

Global Regulatory Compliance Subject Matter Expert and Director of Compliance Consulting

Mr. Rezac is an industry subject matter expert in FDA, EMA and global regulations governing design, construction, commissioning and qualification of cGMP facilities and equipment. Mark contributes to the industry body of knowledge as the co-leader of ISPE's C&Q Community of Practice Steering Team. He has been a frequent presenter at association meetings, conferences and industry events on such topics as "Building Compliance into Facility Design and Construction" (PDA) and "Pharma Manufacturer's C&Q Risk Approach Task Team Forum" (ISPE).

Get Educated. Make a Plan. Be Ready.

Contact us at Annex15@ipsdb.com.

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