



ISPE BASELINE GUIDE VOLUME 5 SECOND EDITION : ADOPTING THE NEW PARADIGM

Facilitator(s)/Moderator(s):

Michael Bogan, President at ICQ Consultants Corp.
Christopher Ciampa, C&Q Validation Engineer at CAI

Presenters:

Deborah Wild, President of DW BioPharma
Michael Polansky, Director of Corporate Quality at AstraZeneca
Jared Marshall, Principal Engineer at Rubius Therapeutics

Webinar Date: Thursday, 18Feb2021
12:00 PM – 1:00 PM

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WEBINAR STRUCTURE AND ABOUT ISPE– MICHAEL BOGAN

Webinar Panel Process and Organization

Michael Bogan and Christopher Ciampa

1. Webinar Structure and about ISPE
2. Opening Statement
3. Introductions to Moderators and Facilitators
4. Introduction to Speakers and Panel Members
5. Topics Discussions
6. Brief Panel Discussion after each Topic
7. Questions from The Audience



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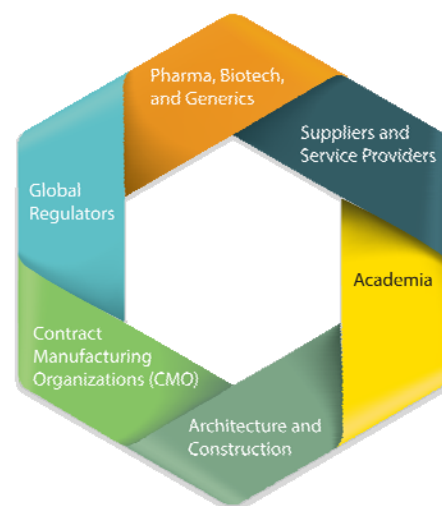
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ISPE is Your Best Professional Advantage

Michael Bogan and Christopher Ciampa

Members represent all facets of the pharmaceutical industry. From design and construction to manufacturing of pharmaceutical products and medical devices, our members come from industries that include:

- Pharma and Biotechnology
- Contract Manufacturing Organizations (CMO)
- Architecture and Construction
- Suppliers and Service Providers
- Generics
- Global Regulators
- Academia



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OPENING STATEMENT - CHRISTOPHER CIAMPA

Adopting the New Paradigm

Michael Bogan and Christopher Ciampa

In 2019, after many years of new guidance updates (which include ASTM E2500, ICH Q8, Q9, 10, as well as FDA Guidance for industry), ISPE updated its paramount baseline guide for Commissioning and Qualification. The purpose of this updated guidance is to define the Baseline® approach for the Commissioning and Qualification of facilities, utilities, and equipment regulated by the FDA.

This will assist in optimizing the commissioning and qualification processes at regulated facilities. Despite this monumental effort, adoption in industry by end users is slow at best and has not been widely accepted. These presentations, and breakout panel discussions by the speakers, will address challenges in adopting the updated methodology, and will also include how to manage change to encourage adoption. The discussion will also include testimonials directly from end users and show how adoption can lead to more integrated qualification approach, allowing for faster project turnaround and cost savings.



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INTRODUCTION TO MODERATORS AND FACILITATORS –
CHRISTOPHER CIAMPA AND MICHAEL BOGAN

Meet your Moderator(s) and Facilitator(s)

Michael Bogan

Michael Bogan has been working in the life science industry for over twenty-five (25) years, supporting operating companies, facility expansions, and green field projects.

He is disciplined, focused and helps organizations meet their business objectives. Michael is recognized by many in the industry as a creative, pragmatic and inspiring leader. He has consistently demonstrated a high level of experience in all aspects of the development, implementation, execution of Quality by Design site level standards and policies at several client sites.



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Meet your Moderator(s) and Facilitator(s)

Christopher Ciampa

Christopher Ciampa has been working in the life sciences industry for over fourteen (14) years. He has experience with Technical Services, Facilities Engineering, Validation, cGMP, and tech transfer. He also has expertise in electrochemistry equipment, water monitoring, laboratory equipment, Computerized Maintenance Management Systems (CMMS), and lab systems. Christopher recently became certified for Computerized Systems Validation (CSV). Christopher has a General Biology (BS) degree from the University of New Hampshire and a Masters in Business Administration (MBA) from Bentley University.



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INTRODUCTION TO SPEAKERS AND PANEL MEMBERS –
CHRISTOPHER CIAMPA AND MICHAEL BOGAN

Meet your Speaker(s) and Panel Members

Deb Wild

Deborah (Deb) is an accomplished C-Suite Executive with over 30 years' experience. Deb has effectively led large groups that include Quality Assurance, Quality Control, Validation, Regulatory Affairs, and Manufacturing departments throughout her career. Deb was a key leader in the development and expansion of Paragon/Catalent Gene Therapy commercial manufacturing facility. Deb is biotechnology and pharmaceutical leader with proven record in bringing products to market and an entrepreneur's perspective as an owner of a successful consulting business.



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Meet your Speaker(s) and Panel Members

Michael Polanski

As a Director of Corporate Quality at AstraZeneca, Mike is the Quality Process Champion for Premises and Equipment, functioning as the primary Quality liaison with Global Engineering in the development of Engineering standards and improved quality focus of Engineering processes. Prior to working in Corporate Quality, Mike was the site lead of Quality Systems and Compliance at AstraZeneca's biopharmaceutical bulk manufacturing facility in Frederick, MD. Over his 23 years of pharmaceutical industry experience, Mike has also held various Quality and CQV roles at Sanofi Pasteur, Centocor, Inc. (now Janssen Biotech) and GlaxoSmithKline. During his tenure at Sanofi Pasteur, Mike was responsible for the successful program development of Integrated Commissioning and Qualification, under the site Engineering function, as the Director of Commissioning and Qualification Best Practices.



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Meet Your Panel Member

Jared Marshall

Jared is a Principal Process Engineer at Rubius Therapeutics where he is responsible for the lifecycle of process equipment and support of GMP operations at the company's Smithfield, RI Red Cell Therapeutics™ manufacturing site. Prior to Rubius, Jared led the process engineering team at Brammer Bio's Cambridge, MA site (now part of Thermo Fisher's Viral Vector Services division) through the transformation, startup, and qualification of the company's first commercial-ready gene therapy viral vector manufacturing facility. Jared has also held site-based and global process and project engineering roles at Biogen and Sanofi Genzyme.



Jared earned a B.S. from Rensselaer Polytechnic Institute in Biomedical Engineering and a M.S. in Engineering Management from Tufts University. He is a past Board of Directors member of the ISPE Boston chapter.



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RELUCTANCE OF INDUSTRY TO START FOLLOWING REVISED BASELINE GUIDE –

DEB WILD

Reluctance of industry to start following revised baseline guide

“It costs money to change”

Are quality systems and other programs nonexistent, mature, or not outlined to an adequate level of detail to allow this strategy?

Examples of aspects of guideline and how to approach:

- ❖ Three things to consider to enact a Life Cycle Approach in your organization
 - ❖ Try simplifying the complex
 - ❖ Develop a requirements library document to better organize critical and non-critical data
 - ❖ Develop critical testing plans (CTPs) and non-critical testing plans (nCTP)



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MANAGING CHANGE – CHALLENGE TO ICQ SUCCESS?

MICHAEL POLANSKY

How Motivated are we to Change to ICQ?

Barriers to Success:



"The significant problems we face can not be solved at the same level of thinking we were at when we created them."

– Albert Einstein



"When something needs to change and there never seems a good time...it means now is the right time to start."

– Unattributed



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Then Change Something...



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• Create a Sense of Urgency:

- needs to answer "Why this? Why here? Why now?"
- needs to be bold and aspirational, yet clear

• Build a Guiding Coalition:

- formed of passionate, skilled and knowledgeable influencers
- cross-functional leaders (by skill not necessarily by position)

• Form a Strategic Vision

- built on a firm understanding of the past and present
- sets the vector to the future, incorporating the benefits as well as risks and sacrifices
- meets "Conditions of Satisfaction" of the stakeholders

• Share the Vision:

- simple, broad-channeled, repetitive and consistent
- must address "What does it mean for me?"
- be open to feed-back: be comfortable with uncomfortable conversations
- builds a "Volunteer Army": momentum of commitment

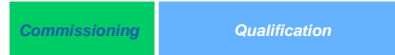


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Setting A Strategic Vision – Understanding Past & Present

Past (V-model):



- Commissioning risks focused on Budget and Schedule.
- Leveraging not a consideration
- Testing resource model back-end loaded
- Risk to Quality deferred to Qualification Phase
- Costly: Highly redundant testing, high frequency of Qualification re-work due to high deviation rate.

Present:



- Risk to Quality managed through introduction of DR/DQ
- "Leveraging" permitted as a retrospective analysis of completed testing
- Quality of engineering test documentation improved (ALCOA)
- Testing resource model approaches even distribution
- Costly: Redundant testing, Qualification re-work, high-deviation rates

Cost Reduction Metric

	Non Leveraged Project	Leveraged Project
Labor Hours / Critical System		
Commissioning	528	693
Qualification	1000	370
C&Q Labor Hours/System		
	1528	1063

Quality (RFT)

	Non Leveraged Project	Leveraged Project
Deviations / Protocol		
Qualification	11.5	6
Validation	11	5



Setting A Strategic Vision – Future State

Future Vision:



- Use of robust Risk Assessment to identify impacts to Quality
 - CQA ← CPP ← CA ← CDE
- Quality oversight focused on product impacting CDE
- Testing resource model front-end loaded (QA, SME and Owner)
- Robust C&Q planning
- Library of standard test scripts to satisfy standard test elements
- Test once at earliest opportunity where risk of retest is low
- Robust execution of GEP end-to-end
- Costs controlled and reduced, low deviation rate and minimized rework

Cost

	Non Leveraged Project	Leveraged Project	Integrated C&Q Project
Labor Hours / Critical System			
Commissioning	528	693	557
Qualification	1000	370	95
Total			
	1528	1063	652

Quality (RFT)

	Non Leveraged Project	Leveraged Project	Integrated C&Q Project
Deviations / Protocol			
Qualification	11.5	6	0.5
Validation	11	5	0.7



ICQ Performance Measurements – Conditions of Satisfaction

Quality Measures – Right First Time:

- Qualification Deviation Target (< X)
- Validation Deviation Target (< Y)

Other Measures:

- Equipment/System OEE – productivity/runtime
- Maintainability (MTTR) and Reliability (MTBF) % improvement.

Cost Measures:

- % Reduction in labor hours/system
- % Reduction in TIC (capital cost)
- Project Schedule Adherence (% on-time delivery by system / by project)
- Procurement benefit (vendor selection and purchasing power)



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DO "TRANSITIONAL" METHODS OF IMPLEMENTATION FROM MORE TRADITIONAL CQV PROVIDE BENEFITS? –

DEB WILD

Do “transitional” methods of implementation from more traditional CQV provide benefits?

Does a resistance to change exist between some of the key stakeholder groups that prevents or limits the execution of the strategy?

- Although this guideline overall will lead to reduction of costs, oversight and resources, and getting there could be costly
 - Ensure corporate “buy-in” for “cost of compliance”
 - Determine the hybrid approach when transitioning already qualified systems and equipment



Do “transitional” methods of implementation from more traditional CQV provide benefits?

- > When would be best time to implement a transition plan?
 - Anytime!



- > Has your organization developed a detailed development plan that outlines the interdependencies detailing leveraging aspects?



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IMPACT OF COVID ON IMPLEMENTATION OF UPDATED GUIDELINE –
DEB WILD

Impact of COVID on implementation of updated guideline – Warp Speed

How to implement a compliant program
simply and quickly

- Determine the engineering deliverables, prerequisites and timing, duration and resource teams needed
- Inputs and outputs need to be thoroughly reviewed to ensure they complement the related task or deliverable



Impact of COVID on implementation of updated guideline – Warp Speed

- Simplification is accomplished by having a in depth understanding of the project deliverables and relationships of interdependent activities. Therefore a few very basic fundamentals need to be established first:

Teamwork – Instill a united goal or “Army of One” mentality

Leadership – Making certain the right people get placed on the right job

Results - Always continue in a forward direction and maintain momentum



“Leadership is solving problems. The day soldiers stop bringing you their problems is the day you have stopped leading them. They have either lost confidence that you can help or concluded you do not care. Either case is a failure of leadership.” – Colin Powell



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QUESTIONS FROM THE AUDIENCE

