

ISPE Boston Area Chapter Presents:

# WEBINAR

## Advancing Pharmaceutical Quality – What's New, What's Next?

*The journey towards enhanced Quality Management Maturity*

**Thursday, March 18, 2021**

12:00 PM – 1:45 PM EST

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### PROGRAM SUMMARY:

Join us for a panel discussion covering what's new with ISPE's Advancing Pharmaceutical Quality Program, FDA updates on quality metrics pilots and quality management maturity, insights on the latest pharmaceutical industry operational excellence benchmarks, and practical strategies for building cultural excellence to support enhanced quality outcomes. Our panel of speakers will address audience questions at the end.

### PROGRAM SPONSORS:



### PROGRAM AGENDA:

- Tami Frederick presents, *"ISPE's Advancing Pharmaceutical Quality Program – Assess, Aspire Act and Advance"*
- Alex Viehmann presents, *"FDA Updates on Quality Metrics Pilots & Quality Management Maturity"*
- Thomas Friedli presents, *"From Quality Maturity to Quality Performance – Databased Insights"*
- Nuala Calnan presents, *"Practical Strategies for Building Cultural Excellence to support enhanced quality outcomes"*
- Facilitated Panel Discussion

### WHO SHOULD ATTEND THIS WEBINAR:

This program is geared towards professionals and managers from Quality, Operations, and/or Strategy Development interested in quality metrics and quality management.

### SPEAKERS:

**Nuala Calnan, PhD, CEO, BioPharm Excel**



Nuala Calnan has over 20 years experience in the biopharmaceutical industry across operations, new product introduction and facility start-up and manufacturing. Nuala's current focus is on the integration of Knowledge Excellence, Operational Excellence, & Cultural Excellence in delivering enhanced quality outcomes for the patient.

Nuala works across the BioPharma and Medtech industries, as well as service providers to these industries, delivering research, consultancy and training that drives innovation. She works closely with industry in assisting organisations to deliver quality excellence, designing metrics that matter to the patient and the business, good data governance programs and implementing behaviour based quality through cultural excellence programs.

Nuala has led a recent Irish Industry research study examining the Product Recall and Quality Defect data at the Irish medicines regulator, HPRA. She is currently a member of the team conducting research on behalf of the FDA examining the role of Quality Metrics in driving enhanced quality performance.

Nuala co-leads the ISPE Quality Culture Team that published the recent ISPE Cultural Excellence Report and the ISPE/ PQLI Task Team on Knowledge Management. She was also lead editor on a recent knowledge management book entitled A Lifecycle Approach to Knowledge Excellence in the Biopharmaceutical Industry, CRC Press 2017.

Nuala is currently an Adjunct Research Fellow with the Pharmaceutical Regulatory Science Team at DIT, Ireland, where she teaches and leads a number of patient-focused regulatory science research projects at Masters and PhD level.

### **Tami Frederick, Sr. Director, Corporate Quality and Cultural Excellence, Perrigo**



Tami is Senior Director of Corporate Quality Systems and Cultural Excellence at Perrigo. She is the Chair of ISPE's Advancing Pharmaceutical Quality team. Tami is a co-author of the 2020 ISPE APQ Series, Quality Management Maturity- CAPA Guide. Tami led the PDA/ISPE Culture Collaboration team authoring the Root Cause Analysis Guide in 2019 and co-authored ISPE Cultural Excellence report in 2017. She is a member of the ISPE Regulatory Steering Team. Tami is Global Quality Leader with 27 years of experience in the Pharmaceutical Industry. She is a chemical engineer by trade and cultural excellence

consultant. Tami has held positions in Corporate Quality, QA & QC Operations, R&D, Operational Excellence, and Technical Engineering. She is a certified Lean Six-Sigma Blackbelt and a Certified Quality Engineer. She is also HACCP certified and a Safe Quality Food Practitioner. Her experience spans solid, semi-solid, and liquid drug dosage forms, API's, Medical Device, and Infant Formula/Foods. Tami has led multicultural Quality teams in the implementation of global quality systems such as global change control, EDMS, SQM, quality investigation and CAPA, corporate quality metrics & governance, global technology councils, and auditing to support compliance. She is a strategic, global continuous improvement leader and change agent advancing the culture of quality throughout all levels in the organization.

### **Thomas Friedli, Director, Institute of Technology Management, St. Gallen University**



Thomas Friedli is a Professor for Production Management at St.Gallen University in Switzerland. His main research interests are in the fields of managing operational excellence, global production management and management of industrial services. He is a lecturer in the (E)MBA programs in St.Gallen, Fribourg and Salzburg. He spent several weeks as Adjunct Associate Professor at the Purdue University in West Lafayette, USA. He leads the St.Gallen OPEX Benchmarking in the Pharmaceutical Industry, the largest independent Benchmarking in this field. He also is the editor, author or co-author of 15

books and various articles. Among his books are "Quality Control Lab", published in 2020, "21c Quality Management in the Pharmaceutical Industry" published in 2018, "Leading Operational Excellence in the Pharmaceutical Industry", published in 2013, "The Pathway to Operational Excellence in the Pharmaceutical Industry", published in 2010 and "Operational Excellence in the Pharmaceutical Industry", published in 2006. Professor Friedli has been the Principal Investigator in a collaborative FDA research grant about quality metrics from 2016 – 2019.

**Alex Viehmann, Director, Division of Quality Intelligence II, FDA, CDER, Office of Pharmaceutical Quality**



Biography coming soon!

**MEETING MANAGERS:**

**Heather Longden**, Waters Corporation

**Charlie Maher**, Resilience

**REGISTRATION FEES:**

**Registration by 03/17/2021**

<input type="checkbox"/> Members	FREE
<input type="checkbox"/> Young Professional Members	FREE
<input type="checkbox"/> Student Members	FREE
<input type="checkbox"/> Nonmembers	\$15

**LOG-ON INFORMATION:**

A confirmation email will be sent one day prior to the webinar with the Zoom login information. Should you have any questions or concerns, contact the office by calling (781) 647-4773 or e-mailing [office@ispeboston.org](mailto:office@ispeboston.org). The webinar can be accessed through phone, online, or through the Zoom webinar app.

**\*\*PLEASE NOTE: CANCELLATIONS RECEIVED AFTER March 17, 2021 ARE SUBJECT TO BILLING\*\***

**REGISTRATION IS NOW OPEN ONLINE!**

Please complete the online registration at [www.ISPEBoston.org/Events](http://www.ISPEBoston.org/Events).

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