LC GC

Data Integrity 2023
A virtual symposium

Monday and Tuesday, March 13 and 14, 2023

Day 1: 10:00 am – 4:30 pm EST

Day 2: 10:00 am – 4:30 pm EST

Event Overview

To ensure that your data integrity programs work, it is essential to keep up to date with current regulatory trends—monitoring both new regulatory guidance documents and trends in non-compliance. In this interactive event, we will ensure that you understand the impact of recent and proposed updates, by addressing four topics:

1. An update on Proposed Regulations for Computerized Systems and Updated FDA Guides
2. Analytical Procedure Lifecycle: How do the draft versions of ICH Q2(R2) and Q14 compare with USP <1220>?
3. Where is USP <1058> on Analytical Instrument Qualification going now?
4. Computer Software Assurance (CSA) versus Computerized System Validation (CSV)

These topics will be discussed within the framework of the data integrity model that sits within the overall pharmaceutical quality system of a regulated laboratory. Analysis takes place at Level 3 in this model, but to ensure both data quality and integrity it is imperative that the elements of the Foundation and Levels 1 and 2 are in place. The analogy of this model is building a house: It collapses if not built correctly.

We will tackle one topic per session. Each session will start with a presentation, which will include a question-and-answer period. This will be followed by an interactive workshop to reinforce the principles of each subject presented. For the workshop portions, participants will be asked to engage in answering questions and sharing ideas—fully anonymously—using a free web-based platform called Mentimeter (menti.com), which can be used through a web browser on any computer or phone. No download or prior preparation is required; the link and a code will be provided during the event.

This virtual symposium on data integrity is aimed at chromatographers and quality assurance professionals who have a working knowledge of data integrity within a regulated GXP laboratory. Thus, basic knowledge, such as an understanding of GMP regulations and ALCOA+ criteria, will be assumed.

Top Reasons to Attend

- *Get up to date with current regulatory trends in data integrity*
- *Understand proposed regulations for computerized systems and updated FDA guidelines*
- *Learn how the draft versions of ICH Q2(R2) and Q14 compare with USP <1220> regarding the Analytical Procedure Lifecycle*
- *Find out where USP <1058> on Analytical Instrument Qualification is heading now*
- *Understand the differences between Computer Software Assurance (CSA) and Computerized System Validation (CSV)—and why you should care*
- *Learn from interactive workshops to strengthen your understanding of these essential concepts in data integrity and how to spot and resolve problems.*

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Agenda: Day One, Monday, March 13, 2023

Session 1: 10:00 am–12:15 pm EST
An Update on New Regulatory Guidance Documents and Recent Regulatory Citations

10:00 am – 11:00 am EST	**Update on Proposed Regulations for Computerized Systems and FDA Guidelines** *Bob McDowall, RD McDowall Ltd, UK* Recently there have been three changes impacting data integrity in regulated laboratories. The first is an updated version of Compliance Program Guide 7346.832 for Pre Approval Inspections; we will examine the main changes and the impact on pharmaceutical R&D. Second, a new version of EU and PIC/S GMP Annex 11 for computerized systems is proposed; we will look at the impact of some of the possible changes for laboratory systems especially for audit trails and their review. Last, we will consider version 2 of the FDA Guidance on Circumstances that Constitute Delaying, Denying, Limiting or Refusing a Drug or Device Inspection. The session will include a live question-and-answer (Q&A) period.
11:15 am–12:15 pm EST	**Interactive Workshop: How Are You Going to Prevent or Solve This Mess?** *Bob McDowall, RD McDowall Ltd, UK* Using citations from FDA warning letters and 483 observations, participants will be asked either what they would have to do to avoid getting this citation or how they would fix the problem. Participants' ideas (shared anonymously) will be compared and contrasted with the teaching team's approach to avoiding or resolving the problem. Throughout this session, attendees will be asked to participate actively using the free web-based platform Mentimeter (menti.com), which can be used through a web browser on any computer or phone (no download required). The outputs of the session will be made available for free download after the training. The session will also include a live question-and-answer (Q&A) period.

Lunchtime Session, 12:30 am–1:15 pm EST
Data Integrity Tools, Tips and Best Practices from Our Sponsors

Leading instrument suppliers give educational 20-minute talks addressing applications, tips, and best practices in ensuring data integrity.

Agenda: Day One, Monday, March 13, 2023

Session 2: 2:00 pm – 4:30 pm EST

Comparison of United States Pharmacopeia General Chapter <1220> with the draft ICH Q2(R2) and Q14 for Analytical procedure Lifecycle Management

2:00 pm – 3:00 pm EST	**Analytical Procedure Lifecycle: How do the draft versions of ICH Q2(R2) and Q14 compare with USP <1220>?** *Chris Burgess, Burgess Analytical Consultancy Ltd, UK* USP chapter <1220> on Analytical Procedure Lifecycle became effective in May 2022 and describes the complete lifecycle in three phases: Stage 1: Procedure Design and Development; Stage 2: Procedure Performance Qualification; and Stage 3: Procedure Performance Verification. Two draft ICH documents on the same subject have been issued for public comment: Q2(R2) on Validation of Analytical Procedures and Q14 on Analytical Procedure Development. The session will compare and contrast the two ICH draft documents with USP <1220>. The session will include a live question-and-answer (Q&A) period.
3:30 pm - 4:30 pm EST	**Interactive Workshop: Implementation of USP <1220> – Challenges and Opportunities** *Chris Burgess, Burgess Analytical Consultancy Ltd, UK* The implementation of a lifecycle approach as contained in USP <1220> is not always easy to accomplish in practice. There needs to be a clear understanding within a company of the technical, compliance, and business advantages to be gained from its adoption as well as the barriers or difficulties to be overcome. A SWOT (strengths, weaknesses, opportunities and threats) analysis approach will be used for this purpose and the process will be explained. An example template will be provided. Attendees will be expected to participate actively in providing inputs for each of the four elements of the SWOT matrix using the free web-based platform Mentimeter (menti.com), which can be used through a web browser on any computer or phone (no download required). The outputs will be made available for download after the training. In addition, a previously generated completed template will be made available and discussed. The session will include a live question-and-answer (Q&A) period.

Agenda: Day Two, Tuesday, March 14, 2023

Session 3: 10:00 am–12:15 pm EST
Update on USP <1058>

10:00 am – 11:00 am EST	**Where is USP <1058> on Analytical Instrument Qualification going now?** *Chris Burgess, Burgess Analytical Consultancy Ltd, UK* Only the United States Pharmacopoeia (USP) has a general chapter on Analytical Equipment Qualification (AIQ), which was last updated in 2018 and saw the integration of AIQ with CSV. Throughout 2022, three Stimulus to the Revision Process (SRP) articles on Analytical Instrument and System Qualification (AISQ) were published for industry comment prior to beginning work on revising this General Chapter. The last of these SRP articles was focused on a lifecycle approach to AISQ where the qualification work required was outlined for Group A, B, and C instruments and systems, including the sub-groups within B and C. Furthermore, more granularity within Group A was proposed: Apparatus with no calibration function and apparatus with no user calibration. The presentation will explain these revisions and look at areas where USP <1058> could be updated. The session will include a live question-and-answer (Q&A) period.
11:15 am–12:15 pm EST	**Interactive Workshop: Analytical Procedure Transfer — What Should You Do to Ensure Success?** *Chris Burgess, Burgess Analytical Consultancy Ltd, UK* Attendees will be given an existing short HPLC procedure to review against the new life cycle approach. Attendees will be asked to participate actively in providing inputs for each of three questions below using the free web-based platform Mentimeter (menti.com), which can be used through a web browser on any computer or phone (no download required): 1. What development documentation would you expect to see to support this procedure? 2. What performance qualification activities would you undertake? 3. What ongoing procedure performance verification activities would you expect to perform The outputs of the session will be made available for free download after the training. The session will also include a live question-and-answer (Q&A) period.

Lunchtime Session, 12:30 am–1:15 pm EST
Data Integrity Tools, Tips and Best Practices from Our Sponsors

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Session 4: 2:00 pm – 4:30 pm EST
Putting What's Wrong with CSV Right

2:00 pm – 3:00 pm EST	**Computer Software Assurance (CSA) versus Computerized System Validation (CSV)** *Bob McDowall, RD McDowall Ltd, UK* Computer Software Assurance (CSA) is part of an FDA CDRH quality initiative and aims to demonstrate that computer software is fit for intended use. The initiative has been developed over 5–6 years in conjunction with industry partners. The problem is that the overall CSA approach publicized that CSV was dead and CSA was the only way forward. However, this changed with the publication of the FDA draft guidance in September 2022, which indicated that CSA will only replace three pages in the existing FDA guidance on General Principles of Software Validation and that CSA must co-exist with CSV. This presentation will review the draft CSA guidance and how CSA and CSV could co-exist for regulated GXP laboratories. The session will include a live question-and-answer (Q&A) period.
3:30 pm – 4:30 pm EST	**Interactive Workshop: How Would You Validate This System?** *Bob McDowall, RD McDowall Ltd, UK* Attendees will be members of a CDS validation team and will be presented with a series of CDS user requirements. Will you test these requirements? If so, how extensively will you do this and how will you justify your approach? If you don't test a requirement, how will you justify this to an inspector or auditor? How will the conservative nature of your QA department impact your approach? How will IT impact your validation approach? Attendees will be asked to participate actively in providing inputs for each of three questions using the free web-based platform Mentimeter (menti.com), which can be used through a web browser on any computer or phone (no download required). The outputs of the session will be made available for free download after the training. The session will also include a live question-and-answer (Q&A) period.

Speakers

Chris Burgess
Burgess Analytical Consultancy Ltd, UK

Chris Burgess is an analytical scientist with more than 48 years of experience in the pharmaceutical industry, initially with Glaxo in Analytical R&D, Quality Control, and Quality Assurance, and then in international consultancy. He is a "Qualified Person" in the European Union. He was appointed to the United States Pharmacopoeia's Council of Experts 2010 to 2015 and re-elected for 2015 to 2020 and 2020 to 2025. He is currently the chair of the USP Joint Sub Committee for the revision of chapter <1058>. He was also a member of the USP Expert Panel on Validation and Verification which generated General Chapter <1220>. He is a visiting Professor at the University of Strathclyde in the Strathclyde Institute of Pharmaceutical and Biomedical Sciences and an editorial board member for *Pharmaceutical Technology Europe* for whom writes the "Statistical Solutions" column.

Bob McDowall, RD
McDowall Ltd, UK

Bob McDowall is an analytical chemist with 50 years of experience, including working in the pharmaceutical industry for 15 years and then working for the industry as a consultant for 29 years. Bob has been involved with the validation of computerized systems for more t han 35 years and is the author of a book on the validation of chromatography data systems. His latest book is *Data Integrity and Data Governance: Practical Implementation for Regulated Laboratories*, published in 2019 by the Royal Society of Chemistry. He is a member of the GAMP Data Integrity Special Interest Group, contributing to the Records and Data Integrity Guide in 2017 and two Good Practice Guides. Bob is also the author of the "Questions of Quality" and "Focus on Quality" columns in *LCGC Europe* and *Spectroscopy* magazines, respectively.