International Alliance for Biological Standardization

# 10th Annual Statistics Workshop:
# Science & Statistics – Elevating CMC through Partnership

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**IBBR, Rockville, USA**

## Automating statistical analysis and GxP reporting (e.g., ICH Q2R2) across the organization

Analytical procedures play a crucial role within the CMC framework. Scientists who develop these analytical procedures must write statistical reports to justify that their method is fit for its purpose. Such reports are crucial for obtaining accreditation for labs or marketing authorization for pharmaceutical products (e.g., as evidence of the drug's correct active substance content). Hence, the reports must also be in line with the current EMA/FDA/ICH/ISO regulation.

However, writing statistical reports is time-consuming and error-prone. Compounding this issue is that scientists developing these procedures often lack the time to perform the analysis thoroughly, while perceiving the regulatory guidelines as more confusing than helpful.

To address these challenges, we developed a framework for automation, to reduce the time required to write these reports from days or even months to just a few minutes, requiring minimal understanding of statistics while, at the same time, ensuring both regulatory and quality (QA) compliance.

The solution requires a strong collaboration and alignment between scientists, statisticians, engineers, IT and QA. We will present the various challenges one may face and how they can be solved:

1. Conducting statistical analyses in accordance with guidelines.
2. Software for automated report writing.
3. Qualifying cloud infrastructure for GxP applications.
4. Complying with quality aspects (CSV\CSA) and (GxP) regulation.
5. Implementing end-to-end process automation.

We will demonstrate through a live real-world case study how we integrated this into a working solution for statistical report writing, suitable for use within GxP contexts. The case study will focus on the new ICH Q2(R2) guideline for analytical procedure validation, although we have other guidelines in the pipeline too, like the USP 1033 for potency bioassays and Q1E for drug product stability. The automation framework is generalizable and can be leveraged to standardize (GxP) reporting across the organization in line with any guideline.