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Tonight on the History Channel: *Bioanalysis—Three Decades in the Making*

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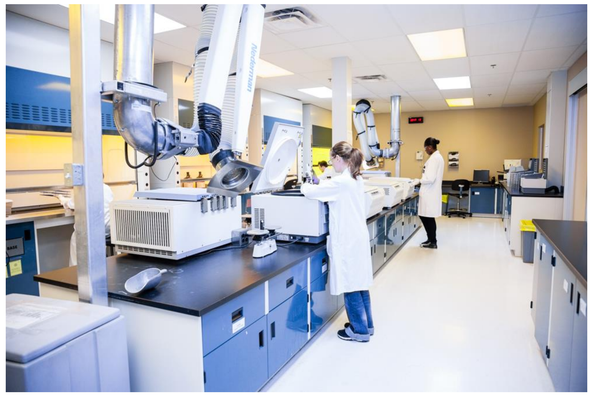
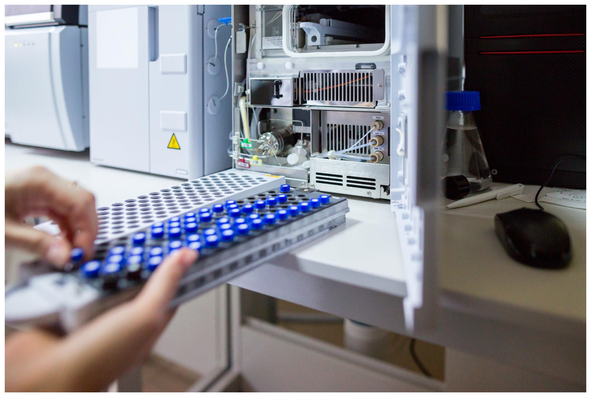
Click here to listen to the recorded poster presentation

ABSTRACT

Starting out as a small gathering of industry representatives in 1990 and evolving through a series of meetings, opinion papers, and guidance documents, the bioanalytical landscape has been shaped over three decades by input from scientific experts, regulatory professionals, and advancements in technology. This poster takes a trip through time from the early days of defining the parameters of method validation through to the latest step in the timeline, the adoption of ICH M10.





1st DECADE

1990

In 1990, a workshop was co-sponsored by the American Association of Pharmaceutical Scientists (AAPS), the United States Food and Drug Administration (FDA), the International Pharmaceutical Federation (FIP), the Health Protection Branch (HPB), and the Association of Analytical Chemists (AOAC). The workshop, held in Crystal City, Virginia, was attended by almost 600 scientists representing the pharmaceutical industry, contract research organizations, academia, and regulatory authorities. In simplest terms, it intended to define a uniform approach in conducting bioanalytical method validations and obtain consistency in regulatory submission expectations. The result of the workshop included an agreement on parameters such as accuracy, precision, selectivity, sensitivity, reproducibility, and stability.

1992

A few years after the workshop, the results were published in the journal, *Pharmaceutical Research*. Specifically, an article entitled, “Analytical Method Validation: Bioavailability, Bioequivalence and Pharmacokinetic Studies,” with Vinod Shah being listed as the first author of the article. The article quickly became the cornerstone of the regulated bioanalytical community and provided guidance for method validation, including specific recommendations for validation, as well as providing acceptance criteria for analytical runs in subsequent studies. Due to the order of the list of authors in the article, many ended up referring to it as the “Shah Paper.”

1999

Almost a decade after the workshop, and with the recognition that the regulated industry was relying heavily on a scientific journal article as its lead, FDA published a draft guidance (in January) entitled, “Bioanalytical Method Validation.” The guidance included many of the elements discussed at the 1990 workshop and subsequently described in the “Shah Paper.”

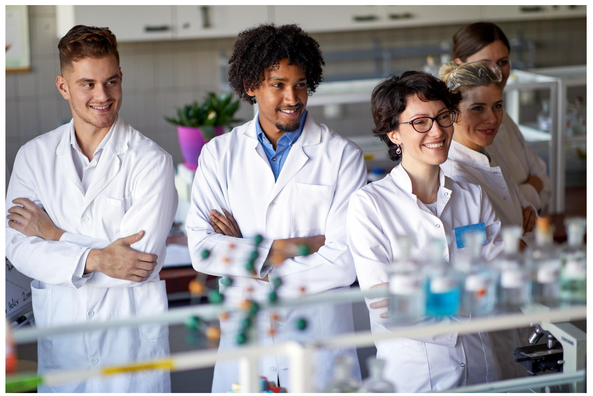
2nd DECADE

2000

It did not take long for the regulated industry to respond, as exactly one year after FDA published the draft guidance, a second workshop was conducted. The workshop afforded the opportunity to discuss FDA’s guidance, but more importantly, to discuss the advances that occurred over the decade—namely, mass spectrometry technology and ligand binding assays. In a similar manner to the first workshop, the results of this workshop were also published in the journal, *Pharmaceutical Research* (in 2001).

2003–2008

As the industry stepped forward into the 21st century, FDA continued its ongoing monitoring of the bioanalytical community. At the center of the FDA’s focus was MDS Pharma, where the lack of the company’s adequate investigations into method reproducibility resulted in several inspections and Warning Letters (2003-2006). Toward the end of the FDA’s inspections of MDS Pharma, industry representatives met (in May 2006) for the 3rd workshop. Based upon the issues at MDS Pharma, incurred sample reanalysis (ISR) became the centerpiece of the workshop, and the industry followed up with a scientific journal article on ISR in 2007 and an ISR-specific workshop in 2008.



3rd DECADE

2012–2018

International influence took center stage as the European Medicines Agency (EMA), the Brazilian Health Regulatory Agency (ANVISA), and Japan’s Ministry of Health, Labor, and Welfare (MHLW) published their own bioanalytical guidances in November 2009, May 2012, and September 2013, respectively. The regulated community responded with requests for harmonization of the multiple guidances. Not to be left off the dance floor, the FDA published a revised draft guidance in September 2013, which incorporated many of the principles seen in the EMA guidance. Following public comment periods for both the EMA and FDA documents, including responses to both documents from SQA Rapid Response Teams, the guidances were finalized in February 2012 and May 2018, respectively.

2019–present

Following significant discussion and recognition of the need for harmonization, the American Association of Pharmaceutical Scientists (AAPS), the Japan Bioanalysis Forum (JBF), and the European Bioanalysis Forum (EBF) collaborated to formally request that the International Conference on Harmonization (ICH) consider supporting harmonization of the various guidances. The ICH published a harmonized guidance (i.e., M10) in 2019. Following a public comment period (including a response from an SQA Rapid Response Team), the final version of ICH M10 was adopted in May 2022, with implementation by FDA in November 2022 and EMA in January 2023.