

Papers

➤ **Analytical methods validation: bioavailability, bioequivalence and pharmacokinetic studies.**

Shah VP , Midha KK , Dighe SV , *et.al.*

Pharm Res. 9, 588 - 592 (1992)

➤ **Bioanalytical method validation - a revisit with a decade of progress.**

Vinod P. Shah, Kamal K. Midha, John W. A. Findlay, *et.al.*

Pharmaceutical Research 17(12), 1551-1557 (2000)

➤ **Validation of immunoassays for bioanalysis: a pharmaceutical industry perspective**

J.W.A. Findlay, W.C. Smith, J.W. Lee, *et.al.*

J. Pharmaceutical and Biomedical Analysis 21, 1249-1273 (2000)

➤ **Workshop on bioanalytical methods validation for macromolecules: summary report**

Krys J. Miller, Ronald R. Bowsher, Abbie Celniker *et.al.*

Pharmaceutical Research 18(9), 1373-1383 (2001)

➤ **Recommendations for the bioanalytical method validation of ligand-binding assays to support pharmacokinetic assessments of macromolecules**

Binodh DeSilva, Wendell Smith, Russell Weiner, *et.al.*

Pharmaceutical Research 20(11), 1885-1900 (2003)

➤ **Workshop/Conference report - Quantitative Bioanalytical Methods Validation and Implementation: Best Practices for Chromatographic and Ligand Binding Assays**

C. T. Viswanathan, Surendra Bansal, Brian Booth, *et.al.*

Pharmaceutical Research 24(10), 1962-1973 (2007)

- **Workshop Report and Follow-Up-AAPS Workshop on Current Topics in GLP Bioanalysis: Assay Reproducibility for Incurred Samples-Implications of Crystal City Recommendations**
Douglas Fast, Marian Kelley, C. Viswanathan, *et. al.*
The AAPS Journal 11(2), 238-241 (2009)
- **European Bioanalysis Forum and the way forward towards harmonized regulations**
Berthold Lausecker, Peter van Amsterdam, Margarete Brudny-Kloepfel, *et.al.*
Bioanalysis 1(5), 873-875 (2009)
- **Incurred sample reproducibility: views and recommendations by the European Bioanalysis Forum**
Philip Timmerman, Silke Luedtke, Peter van Amsterdam, *et.al.*
Bioanalysis 1(6), 1049-1056 (2009)
- **Request for global harmonization of the guidance for bioanalytical method validation and sample analysis**
Philip Timmerman, Steve Lowes, Douglas Fast *et.al.*
Bioanalysis 2(4), 683 (2010)
- **International harmonization of bioanalytical guidance**
Surendra Bansal, Mark Arnold, Fabio Garofolo
Bioanalysis 2(4), 685-687 (2010)
- **Towards harmonized regulations for bioanalysis: moving forward!**
Peter van Amsterdam, Berthold Lausecker, Silke Luedtke, *et.al.*
Bioanalysis 2(4), 689-691 (2010)
- **Bioanalytical method validation: notable points in the 2009 draft EMA Guideline and differences with the 2001 FDA Guidance**
Greame Smith
Bioanalysis 2(5), 929–935 (2010)

- **Regulated bioanalysis and the desire for harmonized regulations in China**
Daniel Tang, Dafang Zhong
Bioanalysis 2(12), 1913-1919 (2010)
- **SQA opinion paper on global harmonization of the bioanalytical method validation guidances**
Christopher Tudan, Stephen Rogenthien, Anthony Jones
Bioanalysis 2(12), 1921-1925 (2010)
- **Building the Global Bioanalysis Consortium – working towards a functional globally acceptable and harmonized guideline on bioanalytical method validation**
Peter van Amsterdam, Mark Arnold, Surendra Bansal, *et.al.*
Bioanalysis 2(11), 1801-1803 (2010)
- **Workshop/Conference Report on EMA Draft Guideline on Validation of Bioanalytical Methods**
Henning Blume, Erich Brendel, Margarete Brudny-Klöppel, *et.al.*
European Journal of Pharmaceutical Sciences 42, 300–305 (2011)
- **Implication of differences in bioanalytical regulations between Canada, USA and south America**
Mark Arnold
Bioanalysis 3(3), 253-258
- **Bioanalytical procedures and regulation: towards global harmonization**
Howard Hill
Bioanalysis 3(4), 365-367 (2011)
- **Bioanalysis in Latin America: where are we and where are we going?**
Rafael Eliseo Barrientos-Astigarraga
Bioanalysis 3(10), 1043-1045 (2011)

- **US FDA/EMA harmonization of their bioanalytical guidance/guideline and activities of the Global Bioanalytical Consortium**
Fabio Garofolo, Josée Michon, Virginie Leclaire, *et.al.*
Bioanalysis (4)3, 231-236 (2012)
- **2012 white paper on recent issues in bioanalysis and alignment of multiple guidelines**
Binodh DeSilva, Fabio Garofolo, Mario Rocci *et.al.*
Bioanalysis 4(18), 2213-2226 (2012)
- **Managing scientific, technical and regulatory innovation in regulated bioanalysis: a discussion paper from the European Bioanalysis Forum**
Philip Timmerman, Neil Henderson, John Smeraglia *et.al.*
Bioanalysis 5(2), 139-145 (2013)
- **The European Bioanalysis Forum community's evaluation, interpretation and implementation of the European Medicines Agency guideline on Bioanalytical Method Validation**
Peter van Amsterdam, Arjen Companjen, Margarete Brudny-Kloeppel *et.al.*
Bioanalysis 5(6), 645-659 (2013)
- **Regulated bioanalysis in Japan: where do we come from and where are we going?**
Noriko Katori
Bioanalysis 5(11), 1321-1323 (2013)
- **Current regulations for bioanalytical method validations**
Mark E. Arnold, Rafael E. Barrientos-Astigarraga, Fabio Garofolo, *et.al.*
Wenkui Li, Jie Zhang, Francis L.S. Tse (ed)
Handbook of LC-MS Bioanalysis: Best practices, experimental protocols and regulations
John Wiley & Sons, Inc. (2013) *in press*

- **A comparison of FDA, EMA, ANVISA and others on bioanalysis in support of bioequivalence/bioavailability studies**
Bradley Nash
Wenkui Li, Jie Zhang, Francis L.S. Tse (ed)
Handbook of LC-MS Bioanalysis: Best practices, experimental protocols and regulations
John Wiley & Sons, Inc. (2013) *in press*

Guidance

- **ANVISA: Resolution- RDC N° 27, Requirements for the validation of bioanalytical methods.**
http://bvsmms.saude.gov.br/bvs/saudelegis/anvisa/2012/rdc0027_17_05_2012.pdf
- **CDSCO: Guidelines for bioavailability and bioequivalence studies**
<http://cdsco.nic.in/html/BE%20Guidelines%20Draft%20Ver10%20March%2016,%202005.pdf>
- **CFDA: Technical guideline for human bioavailability an bioequivalence studies on chemical drug products**
<http://www.cde.org.cn/attachmentout.do?mothed=list&id=167>
- **EMA: Guideline on the investigation of Bioequivalence**
http://www.emea.europa.eu/docs/en_GB/document_library/Scientific_guideline/2010/01/WC500070039.pdf
- **EMA: Guideline on the validation of bioanalytical methods**
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2011/08/WC500109686.pdf
- **EMA: Reflection Paper for Laboratories that perform the analysis or evaluation of clinical trial samples**
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2010/09/WC500096987.pdf

- **FDA: Guidance for Industry: Bioanalytical Method Validation**
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070107.pdf>
- **FDA: Guidance for Industry - Safety Testing of Drug Metabolites**
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm079266.pdf>
- **HPFB: Conduct and Analysis of Comparative BA Studies**
http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/bio/gd_cbs_ebc_ld-eng.pdf
- **ICH: E6(R1) Guideline for Good Clinical Practice**
http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1_Guideline.pdf
- **ICH: Q2(R1): Validation of Analytical Procedures: Text and Methodology**
<http://www.ich.org/LOB/media/MEDIA417.pdf>
- **ICH: M3(R2): Guidance on Non-Clinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals**
http://www.ich.org/MediaServer.jsr?@_ID=5544&@_MODE=GLB
- **MHLW: Draft Guideline on Bioanalytical Method Validation in Pharmaceutical Development**
http://www.nihs.go.jp/drug/BMV/BMV_draft_130415_E.pdf
- **OECD Series on Principles of Good Laboratory Practice (GLP) and Compliance Monitoring**
<http://www.oecd.org/chemicalsafety/testing/oecdseriesonprinciplesofgoodlaboratorypracticeglpandcompliancemonitoring.htm>