# Article information:

Biomarker assay validation | Bioanalysis
[https://www.future-science.com/doi/full/10.4155/bio-2018-0127?rfr\_dat=cr\_pub++0pubmed=Z39.88-2003=ori%3Arid%3Acrossref.org](https://www.future-science.com/doi/full/10.4155/bio-2018-0127?rfr_dat=cr_pub++0pubmed&url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org)

# Article summary:

1. The article discusses the issues surrounding biomarker assay validation (BAV) for clinical trials and regulatory submission.

2. The article provides an overview of the US FDA 2013 draft guidance for industry bioanalytical method validation, as well as a discussion of recent white papers on BAV.

3. The article also includes editorials, commentaries, and research articles that provide insight into parallelism assessments in LBA-biomarker assay development, the current situation on BAV in Japan, necessary considerations throughout BAV, singlicate analysis in LBAs, and potential biomarker applications for hepatic injury and disease.

# Article rating:

Appears well balanced: The article presents the information in a reliable and balanced way, without biases and prejudices. The claims made in the article are well supported and, where applicable, all sides of the argument are given opportunity to present their point of view. The article appears trustworthy and reliable.

# Article analysis:

The article is generally reliable and trustworthy due to its comprehensive coverage of the issues surrounding biomarker assay validation (BAV). It provides an overview of the US FDA 2013 draft guidance for industry bioanalytical method validation, as well as a discussion of recent white papers on BAV. Additionally, it includes editorials, commentaries, and research articles that provide insight into parallelism assessments in LBA-biomarker assay development, the current situation on BAV in Japan, necessary considerations throughout BAV, singlicate analysis in LBAs, and potential biomarker applications for hepatic injury and disease.

The article does not appear to be biased or one-sided; it presents both sides equally by providing an overview of the US FDA 2013 draft guidance for industry bioanalytical method validation as well as discussing recent white papers on BAV from different perspectives. Furthermore, it does not appear to contain any promotional content or partiality towards any particular viewpoint or opinion.

The article does not appear to contain any unsupported claims or missing points of consideration; all claims are supported by evidence from relevant sources such as white papers and workshops. Additionally, all possible risks associated with BAV are noted throughout the article.

In conclusion, this article is reliable and trustworthy due to its comprehensive coverage of the issues surrounding biomarker assay validation (BAV). It presents both sides equally without bias or partiality towards any particular viewpoint or opinion while also providing evidence to support all claims made within it.

# Topics for further research:

* Biomarker Assay Validation Guidelines
* Parallelism Assessments in LBA-Biomarker Assay Development
* Single-Point Analysis in LBAs
* Biomarker Applications for Hepatic Injury and Disease
* Bioanalytical Method Validation Requirements
* Regulatory Considerations for Biomarker Assay Validation

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