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Implementation of Good Laboratory Practices (GLP) in basic scientific research: Translating the concept beyond regulatory compliance

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ABSTRACT

The principles of Good Laboratory Practices (GLPs) are mainly intended for the laboratories performing studies for regulatory compliances. However, today GLP can be applied to broad disciplines of science to cater to the needs of the experimental objectives, generation of quality data and assay reproducibility. Considering its significance, it can now be applied in academics; industries as well as government set ups throughout the world. GLP is the best way to promote the reliability, reproducibility of the test data and hence facilitates the international acceptability. Now it is high time to translate and implement the concept of GLP beyond regulatory studies. Thus, it can pave the way for better understanding of scientific problems and help to maintain a good human and environmental health. Through this review, we have made an attempt to explore the uses of GLP principles in different fields of science and its acceptability as well as looking for its future perspectives.

Contents

1. Introduction

Good Laboratory Practice (GLP) is a quality system that is concerned with organizational process and conditions under which non clinical health and environment studies are planned, performed, monitored, recorded, reported and archived for risk assessment process (OECD, 1997). This quality system enables validity, reproducibility as well as the reliability of toxicity testing data. US Food and Drug Administration (FDA) for the first time in 1978 introduced GLP regulations to eliminate fraud and poor laboratory activities in toxicity studies (Baldeshwiler, 2003). Organization of Economic Cooperation and Development (OECD) introduced GLP guidelines internationally in 1981to facilitate different toxicity studies and to generate quality data for human and environmental risk analysis. The OECD guidelines cover organization, personnel, test facility, quality assurance system, test system, test item, standard operating procedures, performance recording and reporting of study under GLP principles (Turnheim,

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1994). International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), which provides the guidelines for the quality, safety and efficacy assessment of pharmaceuticals has mentioned GLP as a pre-condition for the successful registration of pharmaceuticals internationally (Cavero, 2009). Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) emphasizes that toxicological and ecotoxicological studies should be carried out in compliance with the principles of GLP (Hulzebos et al., 2010). Further, the Globally Harmonized System (GHS) for the classification and Labeling of Chemicals, provides a framework for hazard communication on chemicals emphasizes on the need of GLP complied toxicological studies for the preparation of label and safety data sheet (Morita and Morikawa, 2011). GLP has already been established and felt as a sine *qua non* in regulatory compliance, but the concept must be translated to other areas of science to increase the reliability and reproducibility of the scientific findings.

2. GLP - the basic perception

Scientists generally believe that GLP principles are made for toxicity studies and should be followed only for regulatory compliance. Rather, it is an assurance for the quality system, that the test data are generated under the controlled conditions. GLP regulations and the implementation procedures are extensive and complex in nature. These regulations are not just an approved label or quality symbol to satisfy the study sponsor or the regulatory authorities. The basic intention behind GLP complied studies is to minimize the adverse effects associated with the products as well as to improve the human health and environmental safety profiles. The implementation of GLP principles is voluntary in nature and the basic tenet is to promote good science and to improve the quality of risk assessment process for the safety of humans and the environment. GLP helps to carry out novel analyses called “weight of evidence” carried out by re-examination and re-evaluation of raw data (McCarty et al., 2012). It guarantees point to point transparency, correct interpretation, analysis and conclusion of safety studies. GLP requires transparent, detailed documentation of the laboratory work and explicitly assigns the responsibility for the execution of various steps in an experiment, thereby increases accountability, reduces dishonest practices and enhances reliability (precision) of an experimental data (Buonsante et al., 2014). Recently it has been revealed that the incorporation of GLP guidelines in animal studies for rare disease conditions will further enhance the utility and potential of basic translational science (Wells, 2015).

3. GLP - the concept beyond compliance

It is an established fact that abiding certain documented principles and generating piles of documents will never validate the scientific study. It is an inherent inquisitiveness of the scientific personnel to look into the most valid questions in a particular study. Risk assessment studies are carried out with an objective to explore for a broader perspective and the ultimate focus is of societal benefit. GLP is a resource intensive process, which involves adequate trained manpower to accomplish the assigned job. This concept compels us to do the right job in a right environment by the right people for the right purpose. However, it can never be inferred from the GLP studies that data generated is the best and final; and nothing can be introspected further. GLP compliance studies should allow the discussion regarding validity of a study, to incorporate best judgment in the study results and to finally implement the best outcome of a completed study, just before pushing it to the higher shelf of regulatory compliance. GLP has also been considered as a research management tool, which helps to monitor the study plan, performance as well as reporting stages of a study (Anderson, 2002). This will ultimately help both GLP compliant regulatory studies and the basic scientific research to perpetuate and progress with a true purpose. Thus both regulatory decision making and basic sciences will be benefitted in achieving their respective goals.

4. GLP - the need to achieve quality and reproducibility

The inability to reproduce research findings is a long-standing problem in scientific research. A recent article published in circulation research explored many important areas related to reproducibility issues in basic research as well as in preclinical studies. Further, authors have also emphasized that those institutes which are getting funds for different research activities should come up with GLP regulations. This good institutional practice should work together for a level of cross checking, cross-validation to meet the scientific objectives and could be beneficial in the future as well (Begley and Ioannidis, 2015). An article published in Nature Reviews Clinical Oncology documented that irreproducibility in preclinical oncology research might be due to variables in the complex experimental models, poor documentation procedures, selective reports of the more positive findings, misinterpretation of technical dose for biological outcomes and the extreme cases of data interpretation (Pusztai et al., 2013). The Stroke Therapy Academic Industry Roundtable (STAIR) report outlines the recommendations for the preparation of preclinical study design, which focused the importance of sample size calculations, pre-set inclusion and exclusion criteria, group allocation and blinding screening, appropriate reporting of excluded animals (Macleod et al., 2009). Also reanalysis of data from high-profile microarray based microRNA profiling that were published between July 2011 to April 2012 did not support the original conclusions derived from Minimum Information About a Microarray Experiment (MIAME) database of the studies showing that these studies suffer due to lack of good experimental design and the low quality of data or analyses (Witwer, 2013). Verhagen et al. in their article entitled ‘emphasizing the 10 basic requirements for a scientific paper reporting the anti-oxidant, anti-mutagenic or anti-carcinogenic potential of test substances in in vitro experiments and animal studies’ emphasized the importance of GLP studies to ascertain adequate level of scientific scrutiny (Verhagen et al., 2003). The basic tenet of this concept is to support the resourceful work of the scientists, to reduce the waste from the biased results and to relieve from the need to do sloppy science. Documentation, record keeping and information retrieval are the huge challenges for the proper functioning of GLP to meet the quality and the re-producibility of study results. Scientists have already started giving thoughts on these aspects and efforts have already been made for electronic record keeping, which enables long-term data storage, standardization of ongoing experimental protocols, record archiving to support good scientific practices (Nussbeck et al., 2014).

5. GLP- in chemical risk assessment

Non-clinical studies that are carried out under GLP conditions produce quality data and helps for taking better regulatory decision. The failure of drugs during clinical trials raises question of cost reduction during drug development. More than 50 percent of new medicines of Astrazeneca's failed in preclinical GLP phases of study due to different target organ toxicity issues (Roberts et al., 2014). Although in academics and pharmaceutical sciences many scientific and technological advancement has been achieved, but reproducibility has raised several issues related to the quality and cost of biopharmaceutical research (Scannell and Bosley, 2016).

Adamo et al. suggested the roadmap to conduct the toxicology studies for the successful translation from nonclinical findings to clinical development (Adamo et al., 2012). Appropriate species selection can help in proper dose selection for the GLP toxicology studies as well as to reduce attrition in drug development (Bass et al., 2009). Zhang et al. emphasized that the pre-clinical toxicological and pharmacokinetic studies, which require different analytical methods should be validated with the principles of GLP, prior to the application in regulatory studies for more precision and accuracy (Zhang et al., 2006). Animal experimentation results are not precisely replicated in humans, because of the inherent variability in biological systems. Although clinical and preclinical researches do have their major differences, but lessons learnt from the clinical research should be considered in preclinical research for a more systematic application. However, the conclusions those emerge from the preclinical studies have to be reasonable and validated. When safety pharmacology studies are included into regulatory toxicology studies, experts give their opinion that safety pharmacology endpoints should not be deviated from GLP compliances (Authier et al., 2013). Higgins et al. portrayed the follow up of strategic scenario between discovery *vs* development and in lead optimization process. Further, the authors concluded that close collaboration between chemists, metabolism experts, safety pharmacologists and pharmaceutical formulators are required to ensure a better design and implementation of regulatory GLP toxicology studies (Higgins et al., 2012). It is worthy to mention that the safety of environmental pollutant Bisphenol A raised the question about the scientific validity of GLP principles in risk assessment. When study conducted under GLP complied laboratories Bisphenol A was found safe, whereas many studies conducted under non-GLP environment raised serious concern about the danger of Bisphenol A (Myers et al., 2009). To substantiate the claim that Bisphenol A was safe, Mantovani reported that several inadequacies were observed in the inspected test facility, where the study was conducted and it was finally concluded that the observations should be integrated for a comprehensive risk assessment, especially for endocrine effects (Mantovani, 2002). Further, Vandenberg et al. emphasized that regulatory decisions on endocrine disrupting chemicals should be taken based on the principles of endocrinology only (Vandenberg et al., 2013). Recently Borgert et al. discussed many aspects of data variability between GLP and non-GLP studies for endocrine disruptors and their importance in taking regulatory decision (Borgert et al., 2016). So, scientific conclusions should not be evaluated only based on the compliances of GLP, but also on the weight of evidences and the principle of mechanism of actions at cellular and molecular level.

6. GLP -uses in different scientific studies

World Health Organization (WHO) initiative advocated the quality practices in basic biomedical research. It emphasizes that irrespective of place and purpose of scientific work GLP quality standard should be implemented(Long, 2008). Several scientific publications have raised the serious concerns about the reproducibility and predictability of microarray data. It was suggested that the implementation of GLP principles can help the researchers to generate quality data in microarray experiments, because multistage experimental procedures are involved and each step can influence the quality as well as the reliability of experimental data (Jaksik et al., 2015; Shi et al., 2008). It has been recommended that these principles should be implemented for finished products in pharmaceutical industries to maintain both quality control and quality assurance (Pesez, 1983). Spindler and Seiler emphasized conducting secondary pharmacodynamic and safety pharmacology studies should be conducted as per GLP requirements, especially when results are used for human safety assessment (Spindler and Seiler, 2002). Because of unique feature of immunogenicity and species specificity in biotechnology-derived pharmaceuticals product-specific tests need to be carried out in compliance with the GLP principles (Brunetti, 2008). Besides GMP, emphasis has already been given for the implementation of both GLP and GCP for the production of radio-pharmaceuticals in clinical research due to their specific labels and nature (De Vos et al., 2005). Wolf and Wolfe findings revealed the need of GLP regulations in the studies using fish as an experimental model as this model has emerged as an important toxicological model with better functional genomics, portraying human disease profiles and is also a source of genetically modified food as well as indicators of environmental sentinel (Wolf and Wolfe, 2003). Further emphasis has been made that the data which are obtained from Confocal Laser Scan microscopy and Fourier Analysis by non-pathologists should be accepted for the modernization of classical pathology only by the subjective evaluation and in accordance with GLP principles (Baak, 2002). El Haddad reviewed that for the input of best quality data and the optimization of experimental parameters to perform good analysis for laser induced breakdown spectroscopy to identify potential hazardous material needs the application of GLP principles (El Haddad et al., 2014). Stevenson and Jong advocated several viable options for the incorporation of GLP in microbial and cell culture laboratories (Stevenson and Jong, 1992). GLP was successfully implemented in stem cell bank to establish GLP grade culture, subsequent culture propagation, banking and characterization to establish low-cost, research grade cells, which can be used by a wider research community (Sivarajah et al., 2010). It is recommended that nucleic acid amplification technique requires good assay design and laboratory to avoid technical difficulties such as contamination problems and identification of false positive results (Furrows and Ridgway, 2001). Pre-implantation genetic diagnosis laboratories need good laboratory and quality systems to offer improved clinical outcomes to the patients (PGD, 2008).

Recently a preclinical GLP-compliant safety study was used for the cartilage advanced therapy medicinal product (ATMP), a new class of drug to evaluate bio distribution and tumorigenicity (Zscharnack et al., 2015). The importance of GLP has already been felt in the design and choice of animal models for non-clinical screening of cell-based medicinal products (Lehmann et al., 2015). Emphasis has already been laid for the implementation of GLP based analytical methods to establish high-throughput toxicological and pharmacokinetic studies for some investigational drug candidates (Zhang et al., 2006). The role of GLP has already been enumerated in the execution of cell proliferation studies that include acquisition and validation of imaging and image analysis systems, development and validation of methods for their intended use, formulation and use of standard operating procedures (Dolemeyer et al., 2013). Further, the role of GLP has been highlighted for examining the fetal skeletons in regulatory developmental toxicology studies (Solomon et al., 2016). The importance of good quality assurance practices in molecular pathology laboratory for the estimation of risks and recommendations for diagnostic laboratories has been highlighted (Tembuyser and Dequeker, 2016). Center for Disease Control and Prevention (CDC) gave importance for the successful implementation of GLP for biochemical genetic testing and newborn screening for inherited metabolic disorders (CDC, 2012). Scientists have already felt the importance of GLP in single-cell amperometry studies, a powerful tool for the study of the mechanisms underlying secretion from cells that release electrochemically active substances like catecholamine's, histamine, or serotonin (Machado et al., 2008).

The impact of laboratory practices on inter-laboratory variability in therapeutic drug monitoring has already been highlighted for

immunosuppressive drugs (Christians et al., 2015). Fischer and Dott reported the use of quality assurance and good laboratory practices in mycological laboratory compilation of basic techniques for the identification of fungi (Fischer and Dott, 2002). The GLP concept has been accounted into various analytical measurements such as mass spectrometry for the better outcome of interactions amongst the instrumentation used to perform the weighing and measuring operations and the analysts who perform these operations and subsequently process and interpret the raw data (Boyd et al., 1996). Jones et al. reported the use of Good Automated Laboratory Practices (GALP) for the validation of biologically based electrophysiology data collection systems (Jones et al., 1997). Further, the uses of GLP principles in different scientific fields were discussed in Table 1 with their appropriate inferences and citations.

7. GLP-future perspectives

GLP is complex process and adequate trained personnel are involved to complete a particular study. As science is progressing, regulatory requirements are also becoming stringent day by day

Table 1
Application of Good Laboratory Principles (GLP) in different field of scientific research.

Sr. No	Authors	Title of articles published	References	Inferences
1.	(Shi et al., 2008)	Reproducible and reliable microarray results through quality control: good laboratory proficiency and appropriate data analysis practices are essential	Current Opinion in Biotechnology (2008), 19:10–18	Micro array experiment and data analysis need GLP for better interpretation and conclusion
2.	(PGD, 2008)	Guidelines for good practice in PGD: programme requirements and laboratory quality assurance	Reproductive Biomedicine Online, 2008,16 (1):134-147	GLP is essential for genetic diagnosis and clinical practices
3.	(Furrows and Ridgway, 2001)	Good laboratory practice in diagnostic laboratories using nucleic acid amplification methods	Clinical Microbiology and Infection, 2001,7 (5):227-229	GLP helps in DNA based diagnostic laboratories
4.	(El Haddad et al., 2014)	Good practices in LIBS (laser induced breakdown spectroscopy) analysis: Review and advices	Spectrochimica Acta Part B: Atomic Spectroscopy, 2014,101 (1):171-182	Good Practices are required in analytical laboratories
5.	(Pesez, 1983)	Good laboratory practice in pharmaceutical quality control	Journal of Pharmaceutical and Biomedical Analysis (1983),1 (4):385-391	GLP enhances the quality control of pharmaceutical products
6.	(Boyd et al., 1996)	Mass Spectrometry and Good Laboratory Practices	Journal of American Society for Mass Spectrometry, 1996,7:211–218	Good Practices are required in analytical laboratories
7.	(Tembuyser and Dequeker, 2016)	Endorsing good quality assurance practices in molecular pathology: risks and recommendations for diagnostic laboratories and external quality assessment providers	Virchows Arch. 2016 468 (1):31-41	Good practices are essential for the evaluation of molecular pathology laboratories
8.	(Brunetti, 2008)	Critical aspects regarding the application of GLP principles to new compounds such as biotechnology products	Ann Ist super sAnltà, 2008,44 (4):385-389	GLP facilitates the development of biotechnology based products
9.	(Stevenson and Jong, 1992)	Application of good laboratory practice (GLP) to culture collections of microbialand cell cultures	World Journal of Microbiology and Biotechnology (1992),8:229–235	GLP guidelines an excellent tool for providing authentic & reliable microbial cell cultures and associated data
10.	(Baak, 2002)	The framework of pathology: Good Laboratory Practice by quantitative and molecular methods	Journal of Pathology (2002),198:277–283	New clinical pathological needs, can be met using GLP criteria
11.	(Zhang et al., 2006)	Developing multiple high-throughput GLP methods for an investigational drug candidate in various matrices within a 96-well plate	Rapid Communications in Mass Spectrometry (2006),20:3755–3760	In drug development GLP helps to validate multiple analytical methods for more accurate and precise way
12.	(Zscharnack et al., 2015)	Preclinical good laboratory practice compliant safety study to evaluate bio distribution and tumorigenicity of a cartilage advanced therapy medicinal product	Zscharnack et al. Journal of Translational Medicine (2015),13:160	GLP helps pre-clinical safety and efficacy assessment in a better way
13.	(Christians et al., 2015)	Impact of Laboratory Practices on Inter laboratory Variability in Therapeutic Drug Monitoring of Immunosuppressive Drugs	The Drug Monit. 2015,37 (6):718-724	GLP helps to reduce the inter-laboratory variabilities in therapeutic drug monitoring
14.	(Sivarajah et al., 2010)	The generation of GLP-grade human embryonic stem cell banks from four clinical-grade cell lines for preclinical research	In Vitro Cellular and Developmental Biology—Animal (2010),46:210–216	GLP supports significantly in in vitro developmental biology findings for clinical research
15	(Fischer and Dott, 2002)	Quality assurance and good laboratory practice in mycological laboratory-compilation of basic techniques for the identification of fungi	International Journal of Hygiene and Environmental Health (2002),205:433–442	GLP leads to much more accuracy and consistency in the identification of micro fungi
16.	(Wolf and Wolfe, 2003)	Good Laboratory Practice Considerations in the Use of Fish Models	Toxicological Pathology, 2003,31:53–57	GLP can also be implemented in aquatic animal studies
17.	(Machado et al., 2008)	Good practices in single-cell amperometry	Methods Mol Biol. 2008,440:297–313	GLP can be successfully implemented in cell physiology or pharmacology researches
18.	(Solomon et al., 2016)	Micro-CT imaging: Developing criteria for examining fetal skeletons in regulatory developmental toxicology studies - A workshop report	Regulatory Toxicology and Pharmacology, 2016, 77:100–108	GLP helps in the data reproducibility for developmental toxicological studies
19.	(Jones et al., 1997)	Biologically based validation of PC electrophysiology data collection systems utilizing the Good Automated Laboratory Practices	Qual Assur. 1997, 5 (1):1-17	Good Automated Laboratory Practices (GALP) helps for the easy collection of electrophysiological data
20.	(Dolemeyer et al., 2013)	Regulatory Forum opinion piece: image analysis-based cell proliferation studies using electronic images: the CEPA industry working group's proposal	Toxicologic Pathology, 2013, 41: 1170-1173	GLP should be a pre-requisite for cell proliferation studies used in regulatory compliances
21.	(CDC, 2012)	GLP for biochemical genetic testing and newborn screening for inherited metabolic disorders	MMWR Recomm Rep. 2012, 6, 61:1–44	Centre for Disease Control and Prevention recommends GLP for molecular genetic testing for heritable diseases and conditions

and people's awareness as well as perception for health and environment is increasing, so it is high time to explore individual area and expertise for better interpretation of GLP-complied studies. The histological evaluation of tissue samples is one of the key endpoints of a toxicology study and the results help to define the outcomes and conclusions of a study (OECD Guideline, 1995). Efforts are being made to deliberate the role of toxicologic pathologists in GLP-complied toxicology and carcinogenicity studies (Weber et al., 2014). OECD has taken global initiative to provide guidance to pathologists that how peer review of histopathology should be planned, managed, documented and finally reported to meet the GLP expectations and requirements (Fikes et al., 2015). The critical component in future toxicity screening test with large number of chemicals is to obtain the biological inputs at relevant exposure level with minimum cost, time as well as use of animals. Fundamental changes in the near future are inevitable in both regulatory toxicology and basic science experiments. Regulations in biomedical research impose huge constraints and challenges for the laboratories, managements as well as scientists. There are huge regulatory issues, where scientific personnel have to provide adequate guarantees that protocols are followed adequately, and all the standards are maintained as per the SOPs and all the rules are adhered while implementing the study (Stephens et al., 2013). Hence, there is an urgent need to broaden the scope of GLP principles and to harmonize the concept for better scientific perspectives. A paradigm shift is expected in the near future with the inclusion of genomics in the field of toxicology to meet the challenges of 21st century (MacGregor, 2003; Seidle and Stephens, 2009). The application of GLP standards can be of great benefit to the scientists of all the organizations, where protocols and SOPs can identify any shortcomings for a more successful research. The concept of GLP principles should be translated into basic as well as to applied scientific fields. Any successful experiment needs a good protocol writing, prior experimental design, characterization of test items under investigation, calibration and validation of analytical equipments as well as to record and preserve the experimental data in a most appropriate scientific way for future scrutinization and discussion. At least these concepts must be prevailed and implemented to inculcate good science in the heart and mind of young investigators to sustain and survive the continuity of scientific spirit. It is not important that scientists should know the detail *modus operandi* of good laboratory practice, but it is important that scientists should know what really good science is. Finally, it is worth to remember that the passion for good science should not be lost in a set of defined principles just for the regulatory settings and compliances. At the same time global harmonization efforts are needed to promote GLP as an effective tool to address consistency and transparency in both regulatory studies and basic scientific researches.

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References

Adamo, J.E., et al., 2012. A roadmap for academic health centers to establish good laboratory practice-compliant infrastructure. Acad. Med. J. Assoc. Am. Med. Coll. 87, 279–284.
Anderson, M.A., 2002. GLP Essentials: A Concise Guide to Good Laboratory Practice. Interpharm/CRC.
Authier, S., et al., 2013. Safety pharmacology investigations in toxicology studies: an industry survey. J. Pharmacol. Toxicol. methods 68, 44–51.
Baak, J.P., 2002. The framework of pathology: good laboratory practice by quantitative and molecular methods. J. Pathol. 198, 277–283.
Baldeshwiler, A.M., 2003. History of FDA good laboratory practices. Qual. Assur. J. 7, 157–161.
Bass, A.S., et al., 2009. Exploratory drug safety: a discovery strategy to reduce attrition in development. J. Pharmacol. Toxicol. methods 60, 69–78.
Begley, C.G., Ioannidis, J.P., 2015. Reproducibility in science: improving the standard for basic and preclinical research. Circulation Res. 116, 116–126.
Borgert, C.J., et al., 2016. Does GLP enhance the quality of toxicological evidence for regulatory decisions? Toxicol. Sci. official J. Soc. Toxicol. 151, 206–213.
Boyd, R.K., et al., 1996. Mass spectrometry and good laboratory practices. J. Am. Soc. Mass Spectrom. 7, 211–218.
Brunetti, M.M., 2008. Critical aspects regarding the application of GPL principles to new compounds such as biotechnology products. Ann. dell'Istituto Super. sanita 44, 385–389.
Buonsante, V.A., et al., 2014. Risk assessment's insensitive toxicity testing may cause it to fail. Environ. Res. 135, 139–147.
Cavero, I., 2009. Exploratory safety pharmacology: a new safety paradigm to de-risk drug candidates prior to selection for regulatory science investigations. Expert Opin. drug Saf. 8, 627–647.
CDC, C. f. D.C. a. P., 2012. Good laboratory practices for biochemical genetic testing and newborn screening for inherited metabolic disorders. MMWR. Recommendations and reports : morbidity and mortality weekly report. Recomm. Rep./Centers Dis. Control 61, 1–44.
Christians, U., et al., 2015. Impact of laboratory practices on interlaboratory variability in therapeutic drug monitoring of immunosuppressive drugs. Ther. drug Monit. 37, 718–724.
De Vos, F.J., et al., 2005. The good laboratory practice and good clinical practice requirements for the production of radiopharmaceuticals in clinical research. Nucl. Med. Commun. 26, 575–579.
Dolemeyer, A., et al., 2013. Regulatory Forum opinion piece: image analysis-based cell proliferation studies using electronic images: the CEPA industry working group's proposal. Toxicol. Pathol. 41, 1170–1173.
El Haddad, J., et al., 2014. Good practices in LIBS analysis: review and advices. Spectrochim. Acta Part B At. Spectrosc. 101, 171–182.
Fikes, J.D., et al., 2015. Scientific and regulatory policy committee review: review of the organisation for economic Co-operation and development (OECD) guidance on the GLP requirements for peer review of histopathology. Toxicol. Pathol. 43, 907–914.
Fischer, G., Dott, W., 2002. Quality assurance and good laboratory practice in the mycological laboratory–compilation of basic techniques for the identification of fungi. Int. J. Hyg. Environ. health 205, 433–442.
Furrows, S.J., Ridgway, G.L., 2001. 'Good laboratory practice' in diagnostic laboratories using nucleic acid amplification methods. Clin. Microbiol. Infect. official Publ. Eur. Soc. Clin. Microbiol. Infect. Dis. 7, 227–229.
Higgins, J., et al., 2012. Progressing preclinical drug candidates: strategies on preclinical safety studies and the quest for adequate exposure. Drug Discov. today 17, 828–836.
Hulzebos, E., et al., 2010. An Integrated Assessment Scheme for assessing the adequacy of (eco)toxicological data under REACH. Toxicol. Lett. 198, 255–262.
Jaksik, R., et al., 2015. Microarray experiments and factors which affect their reliability. Biol. direct 10, 46.
Jones, R.D., et al., 1997. Biologically based validation of PC electrophysiology data collection systems utilizing the Good Automated Laboratory Practices. Qual. Assur. San. Diego, Calif. 5, 1–17.
Lehmann, J., et al., 2015. Strategic considerations on the design and choice of animal models for non-clinical investigations of cell-based medicinal products. Bundesgesundheitsblatt, Gesundheitsforsch. Gesundheitsschutz 58, 1215–1224.
Long, D., 2008. Developments in consultancy and training in the GLP arena: 1980 to 2020. A personal view. Ann. dell'Istituto Super. sanita 44, 409–416.
MacGregor, J.T., 2003. The future of regulatory toxicology: impact of the biotechnology revolution. Toxicol. Sci. official J. Soc. Toxicol. 75, 236–248.
Machado, D.J., et al., 2008. Good practices in single-cell amperometry. Methods Mol. Biol. Clift. N.J. 440, 297–313.
Macleod, M.R., et al., 2009. Good laboratory practice: preventing introduction of bias at the bench. Stroke; a J. Cereb. circulation 40, e50–e52.
Mantovani, A., 2002. Criteria for evaluating deviations from good laboratory practice. Ann. dell'Istituto Super. sanita 38, 29–33.
McCarty, L.S., et al., 2012. Information quality in regulatory decision making: peer review versus good laboratory practice. Environ. health Perspect. 120, 927–934.
Morita, T., Morikawa, K., 2011. Expert review for GHS classification of chemicals on health effects. Ind. health 49, 559–565.
Myers, J.P., et al., 2009. Why public health agencies cannot depend on good laboratory practices as a criterion for selecting data: the case of bisphenol A. Environ. health Perspect. 117, 309–315.

Nussbeck, S.Y., et al., 2014. The laboratory notebook in the 21(st) century. EMBO Rep. 15, 631–634.
OECD, 1995. OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring. OECD.
OECD, 1997. OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring. OECD.
Pesez, M., 1983. Good laboratory practice in pharmaceutical quality control. J. Pharm. Biomed. analysis 1, 385–391.
PGD, P.G.D.I.S., 2008. Guidelines for good practice in PGD: programme requirements and laboratory quality assurance. Reprod. Biomed. online 16, 134–147.
Pusztai, L., et al., 2013. Reproducibility of research and preclinical validation: problems and solutions. Nature reviews. Clin. Oncol. 10, 720–724.
Roberts, R.A., et al., 2014. Reducing attrition in drug development: smart loading preclinical safety assessment. Drug Discov. today 19, 341–347.
Scannell, J.W., Bosley, J., 2016. When quality beats quantity: decision theory, drug discovery, and the reproducibility crisis. PLoS One 11 e0147215.
Seidle, T., Stephens, M.L., 2009. Bringing toxicology into the 21st century: a global call to action. Toxicol. in vitro Int. J. Publ. Assoc. BIBRA 23, 1576–1579.
Shi, L., et al., 2008. Reproducible and reliable microarray results through quality control: good laboratory proficiency and appropriate data analysis practices are essential. Curr. Opin. Biotechnol. 19, 10–18.
Sivarajah, S., et al., 2010. The generation of GLP-grade human embryonic stem cell banks from four clinical-grade cell lines for preclinical research. In vitro Cell. Dev. Biol. Animal 46, 210–216.
Solomon, H.M., et al., 2016. Micro-CT imaging: developing criteria for examining fetal skeletons in regulatory developmental toxicology studies - a workshop report. Regul. Toxicol. Pharmacol. RTP 77, 100–108.
Spindler, P., Seiler, J.P., 2002. Quality management of pharmacology and safety pharmacology studies. Fundam. Clin. Pharmacol. 16, 83–90.
Stephens, N., et al., 2013. Closing the regulatory regress: GMP accreditation in stem cell laboratories. Sociol. health & Illn. 35, 345–360.
Stevenson, R.E., Jong, S.C., 1992. Application of good laboratory practice (GLP) to culture collections of microbial and cell cultures. World J. Microbiol. Biotechnol. 8, 229–235.
Tembuyser, L., Dequeker, E.M., 2016. Endorsing good quality assurance practices in molecular pathology: risks and recommendations for diagnostic laboratories and external quality assessment providers. Virchows Archiv Int. J. Pathol. 468, 31–41.
Turnheim, D., 1994. The OECD policy for the implementation of the principles of good laboratory practice. Ann. dell'Istituto Super. sanita 30, 395–400.
Vandenberg, L.N., et al., 2013. Regulatory decisions on endocrine disrupting chemicals should be based on the principles of endocrinology. Reprod. Toxicol. (Elmsford, N.Y.) 38, 1–15.
Verhagen, H., et al., 2003. The 10 basic requirements for a scientific paper reporting antioxidant, antimutagenic or anticarcinogenic potential of test substances in in vitro experiments and animal studies in vivo. Food Chem. Toxicol. Int. J. Publ. Br. Industrial Biol. Res. Assoc. 41, 603–610.
Weber, K., et al., 2014. The role of the pathologist in GLP studies. Toxicol. Pathol. 42, 275.
Wells, D., 2015. Improving translational studies: lessons from rare neuromuscular diseases. Dis. Models Mech. 8, 1175–1177.
Witwer, K.W., 2013. Data submission and quality in microarray-based microRNA profiling. Clin. Chem. 59, 392–400.
Wolf, J.C., Wolfe, M.J., 2003. Good laboratory practice considerations in the use of fish models. Toxicol. Pathol. 31, 53–57.
Zhang, J., et al., 2006. Developing multiple high-throughput GLP methods for an investigational drug candidate in various matrices within a 96-well plate. Rapid Commun. mass Spectrom. RCM 20, 3755–3760.
Zscharnack, M., et al., 2015. Preclinical good laboratory practice-compliant safety study to evaluate biodistribution and tumorigenicity of a cartilage advanced therapy medicinal product (ATMP). J. Transl. Med. 13, 160.