EU – European Medicines Agency

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| Subject | Date | Highlights | PDF / Link |
| Draft Guideline on safety and efficacy follow-up and risk  management of Advanced Therapy Medicinal Products | 01-Feb-2018 | The draft guideline on safety and efficacy follow-up and risk management of Advanced Therapy Medicinal Products  The guideline describes specific aspects of pharmacovigilance, risk management planning, safety and efficacy follow-up of authorized ATMPs, as well as some aspects of clinical follow-up of patients treated with such products. |  |
| Commission Report on Member State penalties for the falsification of medicines | 26-Jan-2018 | This report provides an overview of the Member States’ transposition measures and a qualitative assessment of their effectiveness. The Commission was aided in its assessment by the TRANSPOSE study conducted by an external contractor. The study provided an overview of transposition measures based on information provided by the Member States under Article 118a and from legal experts in the Member States. This was complemented by a qualitative assessment of current penalties relating to falsified medicines, active substances, and excipients. The Commission also consulted Member State competent authorities, through the Expert Group on the delegated act on safety features for medicinal products for human use, for further information on penalties in force. |  |

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| Updated procedural advice clarifies regulatory process for advanced therapy medicinal products | 01-Feb-2018 | The European Medicines Agency (EMA) has updated its procedural advice on the evaluation of advanced therapy medicinal products (ATMPs).  The update aims to streamline some procedural aspects, strengthen collaboration between EMA’s scientific committees and address specific needs of ATMP developers in the evaluation procedure for initial marketing authorizations, to help developers of these medicines – often small and medium-sized enterprises (SMEs) or academic spin-offs – navigate the regulatory process in the EU. |  |
| Q&A  European Medicines Agency pre-authorisation procedural  advice for users of the centralized procedure | 06-Feb-2018 | These questions and answers (Q&As) provide an overview of the European Medicines Agency’s (EMA) advice on issues that are typically addressed in discussions or meetings with marketing authorization holders in the application phase.  This guidance should be read in conjunction with the rules governing medicinal products in the European Union, volume 2, notice to applicantsExternal link icon and pre-submission guidance documents. |  |
| Pharmacovigilance for advanced therapies | Feb-2018 | The page for Pharmacovigilance for advanced therapies has been updated.  On this page are all relevant legislation and guidelines regarding pharmacovigilance in the European Union (EU) apply to advanced therapy medicinal products (ATMPs) Pharmacovigilance for advanced therapies | <http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000297.jsp&mid=WC0b01ac05800862be> |
| Q&A  On bovine spongiform encephalopathies (BSE) and vaccines | 01-Feb-2018 | The questions and answers for Bovine spongiform encephalopathies (BSE) have been updated.  This is an update of the information in the Public Statement on the Evaluation of Bovine Spongiform Encephalopathies (BSE) - risk via the use of materials of bovine origin in or during the manufacture of vaccines and the Questions and Answers on Bovine Spongiform Encephalopathies (BSE) and Vaccines. |  |
| Draft Guideline | 01-Feb-2018 | Draft Guideline on quality aspects included in the product information for vaccines for human use.  This document provides guidance on the pharmaceutical data applicable to product information for human vaccines. It covers information to be provided for the summary of product characteristics, labeling and package leaflet.  The draft will be open for consultation until 31 July 2018 |  |

US - FDA

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| Subject | Date | Highlights | PDF / Link |
| **Warning letter**  Light Age, Inc | 24-January-2018 | Light age is a company which makes medical lasers.  In total 11 violations were recorded, some of them are highlighted below:   * 4 Non-conformances could not be located * Cause was not determined for some NC’s and no Risk Assessment on in the NC’s * Complaints should have a root cause investigation unless an investigation has already been performed, examples of complaints were found without a root cause investigation nor was a rationale given for not performing the root cause investigation * CAPA’s were closed without any rationale * No management reviews were documented for 2015 and 2016 * Firm was not able to provide documentation to demonstrate that you conducted an internal audit of your quality system since 2015 * You have not calibrated or maintained calibration records. A test unit was used during the production of EpiCare Zenith, requires an calibration, however, there were no calibration records for 2014, 2015, and 2016 * Overall the FDA was not satisfied with the response to the 483. The corrective actions that were proposed were not containing any retrospective review of the violations, this is expected as the violations could impact previous produced batches |  |

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| **Warning letter**  Daito Kasei Kogyo Co | 18-Jan-2018 | 2 Violations were recorded and 2 recommendations   * Failure to ensure that, for each batch of API, appropriate laboratory tests are conducted to determine conformance to specifications.   + Products were released without completing all required testing; product identity was therefore not properly identified * Failure to completely report test results on certificates of analysis   + COA was falsified, signing without all tests being performed * CGMP consultant recommended   + Based upon the nature of the deviations we identified at your firm, we strongly recommend engaging a consultant qualified to evaluate your operations and assist your firm in meeting CGMP requirements * Data Integrity Remediation   + Your quality system does not adequately ensure the accuracy and integrity of data to support the safety, effectiveness, and quality of the drugs you manufacture |  |
| **483**  The Wellness Center Pharmacy, Inc | 22-Dec-2018 | A total of 3 observations were made   * Rust like stains were observed in a buffer room ( ISO 7 ) and a metal stool. The metal stool was used during aseptic processing * The mediafil did not closely simulate the aseptic production, also worst case activities were not considered * In the ISO 5 classified area there were overhands that can collect dust |  |

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| **483**  PharMEDium Services, LLC. | 05-Jan-2018 | 16 observations were made in total!! Of these nine were repeats from previous inspections.  From these 16 observations, a few will be highlighted   * Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written, and followed.   + Operators were not showing proper cleanroom behavior. E.G., Leaning over, quick moving, not sanitizing their hands before re-entering ISO 5 area. This is a repeated observation from previous inspections * A review of numerous opened and closed Nonconformances Reports (NCR), noted that it appears that you are not capable of consistently delivering the proper amount of active drug ingredients or diluent to ensure that finished drug products are within acceptable specifications. Therefore, your firm is relying solely on finished drug product testing to release drug products for distribution * Equipment and utensils are not maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product; this observation is also a repeat from a previous inspection * Your firm has had several media fill failures, which indicate that your aseptic techniques are not properly performed. During 2016 and 2017, your firm had a total of9 media fill failures. Your firm's investigations do not properly address the products that were processed by the technicians that failed the media fills. This is also a repeat of a previous inspection * The production area air supply Jacks an appropriate air filtration system, pressure differential was not attained * Container closure systems do not provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product. A lid was not closed for a light-sensitive product * The FDA was not informed on multiple recalls |  |

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| **483**  Empower Pharmacy | 24- Jan-2018 | There is a failure to thoroughly investigate any unexplained discrepancy or failure of a batch, regardless of whether the batch has been distributed, or a failure to expand an investigation to assess other batches that may also be impacted.   * Endotoxin failure was not investigated properly; there was no root cause determined * Potency failure, there was no root cause determined |  |
| **DRAFT GUIDANCE** | Jan-2018 | This guidance is intended to assist applicants preparing to submit to FDA abbreviated new drug applications (ANDAs).  This guidance highlights common, recurring deficiencies that may lead to a delay in the approval of an ANDA.  It also makes recommendations to applicants on how to avoid these deficiencies with the goal of minimizing the number of review cycles necessary for approval. |  |
| **DRAFT GUIDANCE** | Jan-2018 | This guidance is intended to assist applicants in complying with certain labeling requirements for human prescription drug and biological products (21 CFR 201.56 and 201.57). This guidance provides recommendations for applicants developing labeling for new drugs and revising labeling for already approved drugs  The recommendations in this guidance apply only to the product title and initial U.S. approval in  Highlights and do not apply to other parts of the prescribing information, or other types of labeling (e.g., container and carton labeling) |  |

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| **Final Guidance** | Jan-2018 | Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product under Section 503A of the Federal Food, Drug, and Cosmetic Act  To qualify for exemptions under section 503A of the Federal Food, Drug, and Cosmetic Act  (FD&C Act), a drug product must be compounded by a licensed pharmacist or physician who does not compound regularly or in inordinate amounts any drug products that are essentially copies of a commercially available drug product, among other conditions.  This guidance sets forth FDA’s policies regarding this provision of section 503A, including the terms commercially available, essentially a copy of a commercially available drug product, and regularly or in inordinate amounts |  |
| **Guidance Rev 2** | Feb-2018 | This guidance replaces the guidance for industry Microbiology Data for Systemic Antibacterial  Drugs — Development, Analysis, and Presentation issued in August 2016  The purpose of this guidance is to assist sponsors in the development, analysis, and presentation  of microbiology data during antibacterial drug development.  Specifically, this guidance addresses the Food and Drug Administration’s (FDA’s) current thinking regarding the overall microbiology development program needed to support clinical development and approval of antibacterial drugs administered systemically as well as microbiology information collected after approval |  |

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| **Guidance** | Jan-2018 | This guidance sets forth FDA’s policy regarding the mixing,2  diluting, and repackaging of certain types of biological products that have been licensed under section 351 of the Public Health Service Act (PHS Act) when such activities are not within the scope of the product’s approved biologics license application (BLA) as described in the approved labeling for the product  This guidance describes the conditions under which FDA does not intend to take action for violations of section 351 of the PHS Act and section 502(f)(1), section 582, and, where specified, section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 352(f)(1), 21 U.S.C. 360eee-1, and 21 U.S.C. 351(a)(2)(B), respectively), when a state licensed pharmacy, a federal facility, or an outsourcing facility dilutes, mixes, or repackages certain biological products outside the scope of an approved BLA |  |
| **Draft Guidance** | Jan-2018 | This guidance provides information on the implementation of Title VIII of the Food and Drug  Administration Safety and Innovation Act (FDASIA),2 18 titled Generating Antibiotic Incentives Now (GAIN). GAIN creates incentives for the development of antibacterial and antifungal drug products that treat serious or life-threatening infections.  The purpose of this guidance is to provide a resource for information on FDA’s policies and procedures related to the designation of a qualified infectious disease product (QIDP) under GAIN |  |

Worldwide – World Health Organization

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| Subject | Date | Highlights | PDF / Link |
| REVISION OF WHO GMP FOR STERILE PHARMACEUTICAL PRODUCTS | Dec 2017 | The proposal is to replace the text: WHO good manufacturing practices for sterile pharmaceutical products published as Annex 6, WHO Technical Report Series, No. 961, 2011, by the text of the newly revised “EU-PIC/S GMP Annex 1 on the Manufacture of Sterile Medicinal Products” which has reached Step 2 (public consultation).  The new draft EU GMP Annex 1 is made in corporation with the EU, PIC/S, and WHO.  The new draft for the EU GMP Annex 1 will also be adopted by the WHO to replace the current TRS 961 Annex 6. It is an effort from the EU, PIC/S and the WHO to harmonize GMP. |  |

Worldwide – PIC/S

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| Subject | Date | Highlights | PDF / Link |
| EU GMP Annex 1 | December 2017 | Geneva, 20 December 2017: a revision of Annex 1 (Manufacture of Sterile Medicinal Products) of the PIC/S and EU GMP Guides has been prepared in co-operation with the European Medicines Agency (EMA), WHO and PIC/S in order to maintain global alignment of standards, achieving at the same time assurance for the highest quality. The document is subject to parallel public consultation by the European Commission, WHO and PIC/S.  Key changes from the earlier Annex 1 are:   * Introduction of new sections: scope, utilities, environmental and process monitoring sections and glossary * Introduction of the principles of Quality Risk Management (QRM) to allow for the inclusion of new technologies and innovative processes * Restructuring to give more logical flow * Addition of detail to provide further clarity   In line with the PIC/S-EMA Harmonised Consultation Procedure, comments will be collected by the European Commission (EC) |  |

Worldwide – ICH

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| Subject | Date | Highlights | PDF / Link |
| ICH Q12  Draft Step 2b Guideline currently undergoing public consultation | November 2017 | ICH Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management  This guideline applies to pharmaceutical drug substances (i.e., active pharmaceutical ingredients) and pharmaceutical drug products, including marketed chemical, and biotechnological/biological products. The guideline also applies to drug-device combination products that meet the definition of a pharmaceutical or biotechnological/biological product. Changes needed to comply with revisions to Pharmacopoeial monographs are not in the scope of this guideline. |  |