

MONTHLY UPDATE - JANUARY / FEBRUARY 2018

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- **Facility and Excipient Information Shortfalls Identified by FDA As Among Key Contributors to ANDA Review Delays; GDUFA II Driving Expanded Guidance** *p. 4*
- **Expanding Field of Advanced Therapies Puts Pressure on FDA's Review Staff to Keep Pace** *p. 30*
- **Opening Panel at CASSS 2018 WCBP Conference Assesses FDA's 2017 CMC Regulatory Experience with Biotherapeutics and Key Challenges Going Forward** *p. 54*

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US CMC: • Quality Overall Summary • Elemental Impurities Q&A • Pre-Request for Designation • Generic Drugs 2013-17 • 2017 New Drug Approvals • Commissioner on 2017 Approvals • FDA 2018 Priorities • FDA FY 2019 Budget • FDA's 2019 Goals • CDER 2018 Guidances • CBER/CDER Data Standards • Co-Crystals • IND Communications • Product-Specific Guidances • Neurological Therapies • ICH Q11 Q&A • New HHS Secretary

US GMP: • Recall Policies • 2018 Compounding Plan • House Compounding Hearing • House Supply Chain Hearing • Biologics Inspections • Hurricane Maria Drug Shortages

EUROPE CMC: • EMA 2017 Reviews • EMA ATMP Evaluations • UK MHRA Brexit Preparations • UK-Located Firms and Brexit • EMA Relocation • EMA Staffing • SwissMedic on Biosimilar Comparators

EUROPE GMP: • GMP/GDP IWG • MHRA on Unannounced Inspections • MHRA GMDP Symposium

INTERNATIONAL CMC: • ICH Progress Update • Canada/US Harmonization • CFDA on Application Review • CFDA Transparency Guidance • OECD Biotech/Nanotech Definitions • Australian Biological/Biosimilar Nomenclature

INTERNATIONAL GMP: ICRMA Track/Trace • India's CDSCO Changes

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