Your Generics and Biosimilars Industry

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Lisa Parks is the Vice President of Sciences & Regulatory Affairs at the Association for Accessible Medicines. Lisa holds a BS in Pharmacy from the Massachusetts College of Pharmacy in Boston, MA. In her current role, she assists with the development of AAM's Scientific Affairs initiatives. She serves as the primary point of contact for relations with key offices of the FDA and the USP. She is involved with facilitating discussions and efforts on bioequivalence; research and development of drug substance and drug product; IID; emerging technology; quality metrics; CMC; ICH initiatives; and FDA guidance and policy development. She also develops, plans, and coordinates AAM's annual Fall Technical Conference, CMC Workshop, and is involved in developing and planning the science and regulatory session at AAM's Annual Meeting which targets key leaders across the generic drug industry. Lisa served as a key member of AAM's team negotiating with the FDA on the reauthorization of the Generic Drug User Fee Amendments (GDUFA) program and the Biosimilar User Fee Act (BsUFA). Prior to joining AAM, Lisa held key positions in various Offices at the FDA's Center for Drug Evaluation and Research (CDER). She began her FDA career at the Office of Generic Drugs (OGD) as a regulatory filing reviewer, Lisa's ability to drive cross-functional teamwork led her to be appointed as a key representative by the Director of OGD for the initial implementation of GDUFA. She moved on to support the implementation of GDUFA at the Center level and played a key role in the establishment of CDER's new Office of Pharmaceutical Quality.