Laura Castagno, Pharmaceut Reg Affairs 2014, 3:3
http://dx.doi.org/10.4172/2167-7689.S1.016

OMICS Group Conferences
Accelerating Scientific Discovery

4th International Conference on
Pharmaceutical Regulatory Affairs
September 08-10, 2014 DoubleTree by Hilton Hotel Raleigh-Brownstone-University, USA

Active substance master files: What is changing in the EU regulatory framework for drug substances?

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A revised guideline has been recently issued by the European Medicines Agency to assist Applicants, Marketing Authorization Holders and Active Substance Master Files Holders in the compilation of the active substance section of dossiers for a Marketing Authorization Application (MAA) or a Marketing Authorization Variation (MAV) of a medicinal product. Any information that the applicant would like to protect should be contained within the Restricted Part (RP) of the application, while all other scientific information should be included in the Applicant's Part (AP) of the application. "It is emphasized that the AP is still a confidential document that cannot be submitted by anyone to third parties without the written consent of the ASMF holder", explains EMA in the guideline. Knowing the right format, content and procedure to submit Active Substance Master Files properly by EMA or by EU National Competent Authorities is essential to facilitate and accelerate the approval of MAA and MAV in Europe. This presentation describes what's new in the creation, population and submission of ASMF in the EU and highlights the differences and similarities between Active Substance Master Files (EU) and Drug Master Files (US).

Biography

Laura Castagno after graduating in Chemistry and Pharmaceutical Technology from the University of Turin (Italy), gained experience in the Quality Assurance and Regulatory Affairs field with more than sixteen years of activity in multinational pharmaceutical companies in Switzerland. During the past twelve years, she was responsible for submitting Active Substance Master Files and CEP dossiers for both the Helsinn Group and for the FIS Fabbrica Italiana Sintetici Group. She is currently performing the same tasks as a consultant for multiple companies all over the world, while also holding training sessions to educate internal employees.

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