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Third Party Audit and Certification Programmes

Problem statement	Pharmaceutical manufacturers are facing increased regulatory demands to ensure that the raw materials used in their medicines - including excipients - are safe, of high-quality, and sourced from reputable suppliers who adopt appropriate good practices. In turn, excipient suppliers are facing escalating numbers of site audits and related information requests to ensure their facilities and products meet the expectations of regulators. The audit burden on both parties is becoming insupportable, with many suppliers declining audits or only agreeing to host audits on a commercial basis.
Background / Definitions	Credible third party certification involves both an independent assessment declaring that specified requirements pertaining to a product, person, process or management system have been met and also that the certifying body has independent oversight to ensure impartiality and freedom from conflicts of interest. It is more robust than both first-party certification, in which an individual or organization providing goods or services offers assurance that it meets certain claims, and second-party certification, in which association to which the individual or organization belongs provides the assurance. There is an analogous situation regarding audits, that is: •1st party - the supplier audits itself •2nd party - the customer performs the audit or contracts someone to audit on their behalf •3rd party audits – A party who is independent of both the supplier and customer performs the audit – this category includes regulatory audits / inspections. The degree of impartiality of audits increases as follows: $1^{st} < 2^{nd} < 3^{rd}$.
Position	The IPEC Federation believes that independent, third party auditing and certification of excipient suppliers can assist in the development, manufacture and supply of safe and effective medicinal products. The use of third party audit and certification programmes helps to reduce costs, time and resources of both excipient suppliers and users. Such third party audit

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	and certification schemes both raise quality expectations to an industry-accepted level and enhance patient safety. The key principles of third party auditing and certification as supported by the IPEC Federation are: -Excipient site audits are conducted by trained and qualified auditors. The third party provider ensures that its auditors are competent with demonstrated knowledge and proficiency in excipient GMP auditing, prepare thorough audit reports, and understand the audit expectations of the referenced GMP standard. -Excipient audit reports undergo a quality review to ensure clarity, completeness, and in the case of certification, appropriate rating of observation severity. -Excipient certification audit reports are assessed by qualified individuals with the authority to determine if the site meets the requirements for excipient GMP compliance. -Third party certification programmes are assessed for compliance to an international standard such as ISO 17021 or 17065 by a recognized authority. -Third party audit programmes meet the principles of ISO 17021 or ISO 17065 to demonstrate the absence of conflicts of interest and be based on on-site audits that are carried out by qualified, competent organisations. -Certified sites are periodically re-audited by the third party to ensure continuing compliance to excipient GMP. -For schemes such as the 'Pharmaceutical Excipient GMP Audit Sharing System' in Japan where audits are contracted out to the independent GMP Auditing Board for Pharmaceutical Excipients (GAB), audit outcomes are shared amongst its members. The key benefits of third party auditing and certification supported by the IPEC Federation include: -Reduced audit burden for excipient suppliers when a third party audit addresses the need of multiple excipient users. Where the excipient supplier is certified, a copy of the excipient GMP certificate and audit report may suffice to meet the needs of the user as part of its supplier qualification programme. -Reduced audit burden for users. Where a third party supplier audit is available, the user may then shift audit resources to other suppliers. Third party certification involves enhanced audit duration to more fully assess GMP compliance. -Conducting of audits referencing Good Manufacturing Practice (GMP) and

	Good Distribution Practice (GDP) standards, such as the consensus developed NSF/IPEC/ANSI 363-2014 US National Standard[1] and the equivalent EXCiPACT™ standards assures industry acceptance Audit reports and Certifications are generated that are compatible with regulatory initiatives, including but not limited to ○the Falsified Medicines Directive (FMD) ○EU Part 1 GMP Chapter 5 Production (Most recent version) ○ The FDA Safety and Innovation Act of 2012 (FDASIA), which was updated to include "managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug product."[2]
Rationale	Regulatory authorities expect more objective evidence that the excipient supplier has implemented and complies with the principles of GMP in the manufacture of excipients and GDP for distribution of excipients. Increasingly the expectation is that on-site audits are carried out, though the authorities do not mandate that audits must be conducted by the 2nd party. Properly executed third party audit and certification programmes which meet the IPEC Federation's position and expectations deliver benefits to excipient suppliers and users - as well as regulators - by reducing audit burden without any compromise in patient safety.

About IPEC Federation:
Created in 2010, the IPEC Federation is a global organization that promotes quality in pharmaceutical excipients. The IPEC Federation represents the four existing regional International Pharmaceutical Excipient Councils (IPECs) – IPEC-Americas, IPEC Europe, IPEC Japan and IPEC China – and provides a unified voice to promote the best use of excipients in medicines as a means of improving patient treatment and safety. Its global membership extends to more than 200 companies.

[1] The U.S. FDA participated in the development of NSF/IPEC/ANSI 363-2014 US National Standard and Japan's GAB conducts audits at the request of individual excipient manufacturers and pharmaceutical companies using the IPEC Japan GMP Guide 2006.

[2] These new requirements are designed to improve product quality related to the qualification and supervision of excipient manufacturers and distributors. These state that qualification of excipient suppliers should include a risk assessment, and this can take into account any certifications held.