

PRESS RELEASE

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Global Pharmaceutical Excipient Service Providers Agree to Collaborate

There is a need and growing regulatory pressure to help a very large and diverse range of pharmaceutical excipient suppliers worldwide to demonstrate their manufacturing and distribution competences and achieve recognition through qualification against common standards. Three international organisations – Excipact, Rx-360 and IPEA Inc – are pleased to announce that they have agreed to help to improve patient safety and security of the global supply chain for pharmaceutical excipients by using a self-regulated and voluntary audit scheme based upon the widely accepted IPEC-PQG GMP and GDP Guides. The audit scheme is based upon the new Excipact standard (schedule for launch in 2011) and the forthcoming equivalent ANSI NSF363 standard.

The Excipact standard builds on the existing ISO 9001 Quality Management System Standard to add a standard that covers the additional requirements necessary for GMP and GDP Certification. The aim has been to develop a global voluntary standard against which pharmaceutical excipient manufacturers, suppliers and distributors can be certified by appropriately qualified 3rd party certification organisations to obtain GMP and GDP certificates. This process will also generate expert audit reports for the benefit of auditees and their customers internationally.

The Excipact equivalent ANSI NSF363 standard provides a stand alone standard based on the IPEC PQG GMP guide that can be used for GMP certification of companies that are not ISO 9001 registered or who prefer to have their GMP audit separate from their ISO 9001 audits. IPEA, who currently provides 3rd party Excipient GMP audits and issues Excipient GMP Certificates under their ANSI Accreditation, plans to use the ANSI NSF 363 Standard for certification once it is officially adopted. Excipact GMP and GDP Certificates will only be issued for audits conducted using auditing firms under licensing agreement with Excipact.

Rx-360, using contracted auditing firms, will audit excipient manufacturers, suppliers and distributors against the Excipact standard for the purpose of generating shared audit reports.

A common feature of the collaboration will be to ensure that audits to these standards are conducted by appropriately trained, qualified and competent assessors to meet the demanding needs of the pharmaceutical industry and that each organisation will facilitate the sharing of audit reports with interested parties.

Notes for Editors

1. **Excipact** started in May 2008 and developed as an international group of organisations representing excipient manufacturers, suppliers and distributors, viz., EFCG (European Fine Chemicals Group), FECC (European Association of Chemical Distributors), IPEC Europe and IPEC Americas (International Pharmaceutical Excipients Council), and PQG (Pharmaceutical Quality Group). Currently Excipact is in operating under the IPEC Federation while they are in the process of forming a legal entity to administer the audit protocol and to issue certificates.

The Excipact standard has been developed for organisations that hold, or plan to hold, ISO 9001 and is scheduled for launch in 2011. As an alternative, a comparable US national standard that combines the elements of ISO 9001 and Excipact is being developed by ANSI-NSF for launch in 2011. Therefore, organisations either with or without ISO 9001 certification will be able to obtain pharmaceutical excipient GMP and GDP certification from 2011.

2. **Rx-360** is an international supply chain consortium formed in 2009 to help improve supply chain security and to help its members to reduce the number of audits by a process of sharing audit reports. From mid-2011, Rx-360 will offer its members an audit of a pharmaceutical excipient supplier with the generation of a comprehensive audit report which can be used by its members to qualify the supplier.

3. **IPEA Inc.** is a US-based international 3rd party certification and audit service provider to the international pharmaceutical manufacturers and excipient producers. IPEA is accredited by ANSI to provide certification to the IPEC-PQG excipient GMPs but also offers an audit-sharing system based on audits against the IPEC-PQG GMP Guide. IPEA plans to replace the Guide with the new ANSI-NSF standard, intended to be Excipact-equivalent, when it is published in 2011. IPEA offers an expert audit report to auditees and users of excipients to aid their qualification processes.