UNIVAR®
PHARMA
INGREDIENTS

Univar's excipient manufacturer audit library

Chemistry Delivered™

Chemistry Delievered.™

Comprehensive auditing of excipient suppliers can be a challenge for drug and nutritional supplement manufacturers. APIs and other high-risk areas are a priority for regulatory resources, often at the expense of regular excipient audits. But, with a growing focus on the GMP compliance of excipient manufacturers, and increasing adoption of the IPEC GMP guidelines internationally, monitoring of excipient production is receiving more regulatory attention: the FDA is expected to start conducting more frequent excipient reviews.

Since excipients are used in nearly every drug and / or nutritional supplement formulation, excipient manufacturers can be faced with an enormous volume of audit requests. Many have limited audit dates available — some have even begun to charge a fee to perform an audit for all but their largest customers.

Univar's innovative audit library can help your company navigate the supplier auditing process.

We are in a unique position in the industry, representing the broadest excipient portfolio from respected producers. Univar has contracted a certified third party to conduct audits of these major excipient partners, using the IPEC-PQG GMP Guide for Pharmaceutical Excipients. The audits are collected in our audit library and made available to our customers.

The library's audit packages include the initial audit, observed non-conformances, and the excipient producer responses. Audits will be scheduled on a three-year rotation — sooner if conditions warrant.

To learn more, please contact your Univar pharmaceutical specialist.

OFFERING CERTIFIED EXCIPIENT MANUFACTURER AUDITS TO IPEC GUIDELINES

- Audits available to every Univar customer
- Conducted by qualified third party auditor
- Comprehensive reports
- Customized access

BENEFITS OF UNIVAR'S AUDIT LIBRARY

- Audits available when needed
- Regular updates, long-term solutions
- Frees internal regulatory resources

COST-EFFECTIVE APPROACH

- Single audits, or multiple audit packages available:
- 2 – 4 audits over two years
- 5+ audits over three years

Completed and scheduled audits

Supplier	Products	Audit date	
Ingredion	Liquid sorbitol 70%, liquid maltitol, crystalline sorbitol	04 2009	12 2012
Covidien (Mallinckrodt)	Magnesium and calcium pharma stearates, sodium and potassium phosphates	10 2009	01 2013
Innophos	Dicalcium phosphates, pharma grade	10 2009	12 2012
Dow	CARBOWAX™ solids — St. Charles, LA	05 2010	05 2013
	CARBOWAX™ liquid — Plaquemine, LA	05 2010	05 2013
Dow	METHOCEL™ Premium — Plaquemine, LA	12 2010	08 2013
	METHOCEL™ Premium — Midland, MI	09 2010	Q1 2014
Ineos	Ethyl acetate — Hull, UK	02 2011	
P&G	Glycerine – Cincinnati	02 2011	
Calumet	Mineral oil and petrolatum — Karns City, PA	06 2011	
	Mineral oil and petrolatum — Dickinson, TX	06 2011	
Oxiteno	Alkest (sorbitan monolaurate and polysorbate)	09 2011	
Lyondell	Propylene glycol USP	03 2012	
Honeywell	Acetone NF	03 2013	
Exxon	IPA USP	05 2013	

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Printed on paper made with 20% post-consumer waste.

20131126