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GMP UPDATE 2018
SEMINAR

Announcing a 1-day meeting to review the major changes and developments in GMP which have occurred during 2018 and which are expected to have a significant impact on compliance in the future

Dear Colleague,

PCS are pleased to announce this annual event addressing the changes to current Good Manufacturing Practices that have occurred in the preceding year or are expected in the near future. This well-attended annual meeting offers participants the opportunity to review, discuss and exchange views on emerging GMP trends and issues. We are pleased, therefore, to invite you to this year's

GMP Update 2018 to be held at the Mitland Hotel, Utrecht on Tuesday, December 11th, 2018. From 09:00 to 17:30 with a complimentary network drink after the seminar has concluded.

A number of GMP developments have already taken place in the first half of this year. There is every expectation that by the end of the year 2018 there will be further news to report. At the time of writing, it is expected that the December event will include:

- Revisions to the EU GMP including Annex 13, Part IV and the draft of Annex 1.
- Updated sections of the USP and EP. Including EDQM guidances on Qualification of Equipment, Liquid Chromatography and Mass Spectometry
- FDA Regulatory Update, including Nano Material Requirements, Compounding Drug Products and Labelling.
- WHO Regulatory Update
- The MHRA Data Integrity Guideline and Quality Culture
- ICH Q-12 Lifecycle Management
- PIC/S Expected Revision of Chapters 3, 5 and 8 as well as the Aide-Memoire on Cross-Contamination in shared facilities.

TARGET AUDIENCE

This meeting will be of benefit to all personnel interested in keeping up to date with current GMP developments, and contributions will be made in Dutch. Early registration is recommended. Participants who register before September 1st of 2018 will receive a 10% early registration discount. Group discounts apply.

REGISTRATION INFORMATION

The cost for this seminar is €810,- ex. VAT.
Please register on our website **www.pcs-nl.com** or send your name, company and function to **info@pcs-nl.com** or call **+31 (0)182 503 280**

The meeting will be led by government, industry and regulatory experts from the Netherlands.

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GMP UPDATE AGENDA 11 December, 2018

Start - Einde	Onderwerp
08:15 09.10	Registratie
	Seminar Introductie
	EU - Annex 13 - Investigational Medicinal Products (IMP)'s
	EU - Part IV – Advanced Therapeutical Medicinal Products (ATMP)'s
	EU - Annex 1 Draft – Interpretation by PCS
	EU - Questions & Answers – The Highlights
	Inspectie voor de Gezondheidszorg en Jeugd (IGJ) Update
	European Pharmacopoeia & USP • EDQM – Qualification of Equipment • EDQM – Liquid Chromatography • EDQM – Mass Spectometry • EDQM – Computerized Systems Validation + Annex 1 + Annex 2
	World Health Organization (WHO) Update
	FDA • Labelling Requirements • Compounding Drug Products • Good ANDA Practices • Nano Materials in Medicinal Products • 483 & Warning Letter Trends
	ICH – ICH Q-12 Lifecycle Management
	PIC/S • Working Group for Revision Annex 2 • Revision of Chapter 3, 5 & 8 • Aide Memoire on Cross-Contamination in Shared Facilities
	MHRA Data Integrity Guidance (In-Depth) & Quality Culture
	Process-Centered Design
	Slotwoord + laatste discussie
17.30	Borrel

Onder voorbehoud van wijzigingen

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