GMP NEWSLETTERS

News: GMP Inspections/Audits

19.03.2014
FDA issues Import Alert for two Chinese Companies
The US FDA and the European Union have increased their GMP Inspection Systems sign ult
inspections are being performed outside their own territory. Now the FDA has issued an I o
manufacturers. Read more about the FDA Import Alert.

05.03.2014
FDA: More Inspections in India
During her visit in India, FDA Commissioner Margaret A. Hamburg stated that inspections in India will be incre
more.

05.03.2014
Indian Regulators promote two levels of GMP
GMP deviations and even data falsification have been identified in a it p
interpretation of FDA and EU authorities on one side and the Indian com
different picture? Read more in our GMP News

11.02.2014
What is FDA Readiness exactly?
Many pharmaceutical companies would like to achieve a so-called "F und
under this term? Read more here.

29.01.2014
85 Company listed with GMP-Non Compliance Statements in the Ne
As already reported, the EMA has started listing so-called GMP Non GM
database in addition to Certificates of GMP Compliance. Now, detail y
available.Read more in the News.

29.01.2014
FDA: more Inspections in 2014
With their new budget, FDA will be able to increase drug plant inspections worldwide and especially in China.

18.12.2013
FDA plans significant increase of GMP Inspections in China

For quite some time, the US FDA has elaborated concrete plans to increase the number of inspections in Chi
plans were developed as a consequence of the Heparin crisis. Bas US
now increase the number of inspections significantly. Read more.

24.10.2013
How to share Audits
Because of ongoing globalisation and outsourcing activities, more a p
saving resources is sharing an audit. Read more about a service o

24.10.2013
FDA publishes List of GMP facilities producing for the US market (
The US FDA has published a comprehensive list of facilities that pr de

Quality Assurance
GMP in Biotechnology
Microbiology
Regulatory Affairs
GMP in Pharmaceutical Development
Quality Control

Generic Drug User Fee Act. Please read more about this list.

- Storage, Distribution, Transportation
- Sterile / Aseptic Manufacturing
- Computer Validation
- Technical Operations
- GMP for APIs and Excipients
- Validation
- Medical Devices

22.10.2013
New FDA Requirement on the Handling of INDs
A new FDA document is supposed to provide a consistent approac ti
drug applications (INDs) within the Center for Drug Evaluation and oc
the FDA as well as the communication with the applicant. More inf

04.09.2013
New FDA Regulation gives the Agency more Power during an Insp
FDA is proposing a regulation to implement administrative detention authority during inspections, which might
new risk to facilities. Read more.

28.08.2013
Frequently asked GMP question: How should active substance auditors be qualified?
From time to time we receive "GMP questions" from ECA Members. Please read the anwer to this question i
News

10.07.2013
Frequently Asked Question: How important is Accreditation for Supplier Audits
We regularly receive questions related to GMP compliance issues. One of the most asked question addresse
accreditation of bodies that perform Third Party Audits. Read more in the GMP News.

03.07.2013
FDA publishes new GMP Guide for Cosmetic Products
On June 25, 2013 the US FDA published a new Good Manufacturing Practice Guide for Cosmetic Products. R
more here.

03.07.2013
QbD and RTRT - New Question and Answers published by EMA
The level of cooperation between inspectors and assessors when handling "QbD" applications involving RTR
Time Release Testing) was added to the Q&A part of the EMA's website in June 2013. More information can
the News.

19.06.2013
MHRA implements new Software for risk based Inspection Planning
Medicines regulator implements innovative software to analyse risk data and target inspection activity. Read m

27.02.2013
Are 300 GMP Inspections necessary by 2 July 2013?
The heads of the EU authorities for medicines are organised in a group called Heads of Medicines Agencies.
which took place in Dublin just recently, the Committee identified the need for GMP inspections to be conduct
manufacturing sites by the 2nd of July 2013. Read more.

20.02.2013
India opens Drug Inspection Office in China
India wants to open its first drug inspection office in Beijing, China on 01 March 2013. Read more.

13.02.2013
Up to $190.389 for FDA's New Inspections Fees
Many in the GMP environment haven't realised the consequences of the so-called Generic Drug User Fee Ac
yet. The FDA has now published the exact fee rates for facility inspections. Read more here.

12.12.2012
Swiss GMP standards and inspection equivalent to EU
The EU Commission has announced on 22 November 2012 that Switzerland has been listed as the first coun

equivalent standards in the manufacture of active pharmaceutical ingedients (APIs) to those of the EU. Click h
more

10.10.2012
GMP Matrix as Standard for Audits in many Companies

The European Compliance Academy developed a so-called Good Practice Gu
some years ago. It is a juxtaposition containing the requirements laid down in t
GMP Guide, FDA's cGMP Guide and ISO 9001. Read more here.

10.10.2012
What are the consequences if an API manufacturer has not been audited?
The Danish Medicines Agency offers some very helpful Question & Answer documents on their webpage. Ple
theanswer to this question here.

04.10.2012
Which Types of Third Party GMP Audits may be used - which not?
We are often consulted about the acceptance of GMP audits of API manufacturers. The point is that more and
organisations offer such audits. What is essential to pay attention to? More details can be found here.

04.10.2012
Qualified Person Association Database for Shared Audits "QPSHARE" comprises 284 API and Excipient Sup
In 2010 the European QP Association initiated the shared audits database "QPSHARE". With this database th
Association wants to support European QPs in identifying suppliers other QPs are possibly interested in as w
way facilitates sharing audits. Read more.

29.08.2012
New Templates for GMP and GDP certificates published by EMA
In May 2012 and in July 2012 the European Medicines Agency (EMA) revised the Compilation of Community
on Inspections and Exchange of Information. Read more here.

01.08.2012
Another Third Party GMP Audit performed in Germany by API Compliance Institute
The API Compliance Institute co-ordinates so called Third Party Audits. On behalf of one or several QPs, GM
performed at API manufacturers. Some audits are made available for companies who were not involved in the
sponsoring of the audit. These GMP audits are called shared audits. Please find more information about the la
Audit.

25.07.2012
More GMP Inspections by EMA due to Increasing Quality Issues
In its annual report 2011, the European Medicines Agency (EMA) reported about the number of inspections p
that year. Go here to read more.

20.06.2012
EMA updates "Compilation of Community Procedures on Inspections and Exchange of Information"
In the light of recent events, the EMA has updated its "Compilation of Community Procedures on Inspections
Exchange of Information". Some documents concerning GDP have been added to this compilation of procedu
not only interesting for inspectors. For more information read here.

13.06.2012
Two Third Party GMP Audits performed in Germany by API Compliance Institute
The API Compliance Institute recently performed Third Party GMP Audits at two API manufacturing sites in G
The Audits were initiated by a group of Qualified Persons and QA Managers from different pharmaceutical co
who are using the respective APIs to manufacture their medicinal products. Please read more here.

11.04.2012

PIC/S publishes Aide-Memoire on Inspection of Risk Management Systems
The PIC/S has recently published an Aide-Memoire for GMP inspectors on inspections of quality risk manage systems that became effective on 2 April 2012. Read more here.

04.04.2012
International Collaboration on Good Manufacturing Practice Inspections expanded
The ongoing collaboration on good manufacturing practice (GMP) inspections of active substance manufactu between the European Medicines Agency and its international partners is to be expanded. Read more.

14.03.2012
Regulatory Monitoring of API Manufacturers - FDA, TGA, EMA and EDQM express Common Objectives for I Collaboration
The international programme on cooperation on GMP inspections of API manufacturers by regulatory authorit be continued and extended. The EMA has published a document which defines the rules for collaborations ar information sharing between the authorities. Read more here.

12.01.2012
New Version of ISO 19011 on Auditing published
ISO has published an updated edition of the ISO 19011 auditing standard. ISO 19011:2011 provides guidanc conduct of internal or external management system audits, as well as on the management of audit programm find more information here.

21.12.2011
New FDA and EMA Initiative allows mutual Recognition of Inspections
A new EMA/FDA initiative should enable the authorities in the European Economic Area (EEA) and the US to results of inspections performed in each other's territories. Read more.

02.11.2011
International Information Sharing is Impacting FDA Inspection and Enforcement Decision-Making
As International Pharmaceutical Quality (IPQ) reports in its September issue, the growing information sharing globe has an increasing impact on the US Food & Drug Administration's (FDA) inspection decision-making a activities.Read more.