PHARMACEUTICAL SUPPLIER QUALITY FOR THE 21ST CENTURY

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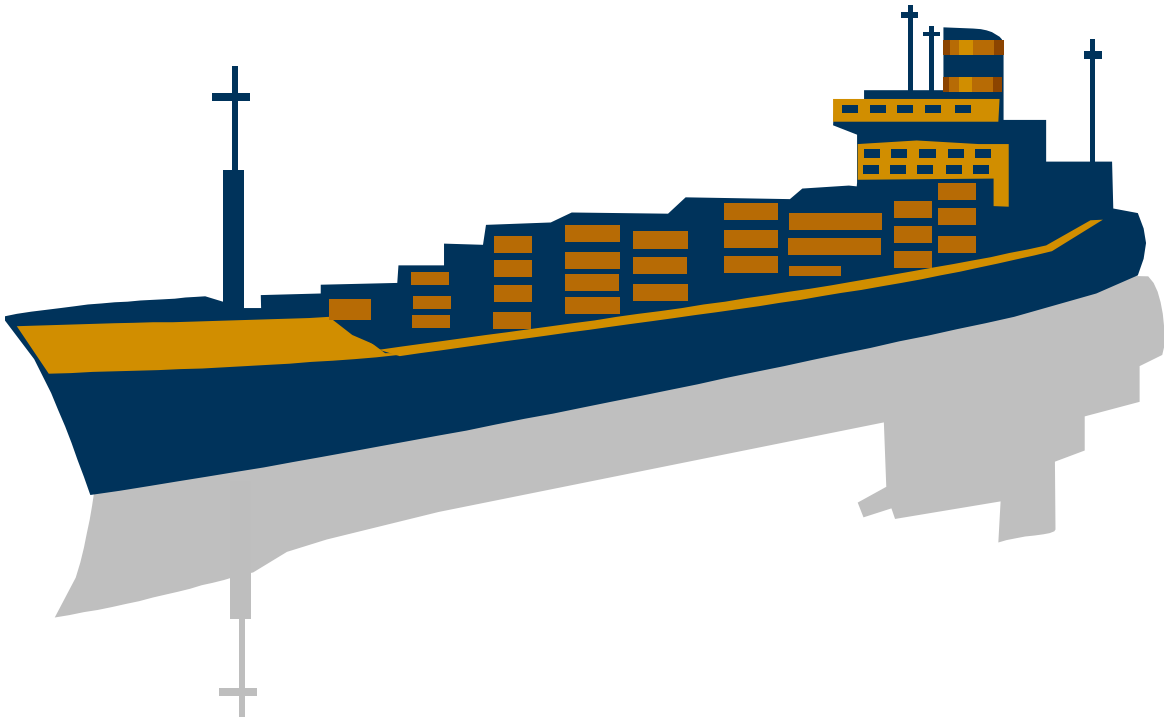
PDA New England Dinner Meeting
March 13, 2013, Burlington, MA.

6 million shipments of FDA-regulated goods in 2001



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GLOBALIZATION

~ 24 million shipments of FDA-regulated goods passed through the 300 U.S. ports of entry in 2011

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BEFORE ……

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NOW ……

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INTENTIONAL ADULTERATION OF API'S AND RAW MATERIALS

aka ECONOMICALLY MOTIVATED ADULTERATION

from unknown and unverified supply chain:

- Heparin contaminated with OSCS deaths 2007-2008
- Repeated Glycerin DEG contamination - deaths
- Melamine adulterated nitrogenous raw materials (pet food and milk products - deaths)
- Contaminated gelatin capsules in China 2012

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It's a jungle out there!

We don't know what's **next!**

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IT'S A JUNGLE OUT THERE!

We should only use **approved suppliers**!

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SUPPLY CHAIN FOR MOST MATERIALS OTHER THAN API'S IS UNKNOWN TO MANY CUSTOMERS

- Often many brokers and distributors involved
- Some suppliers get materials from brokers who change sources at any time to cut costs
- FDA does not yet require brokers of excipients to register
  - very few of them have ever been inspected
  - brokers not disclosed by other registrants
- C of A does not show where testing was done

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Globalization and complex supply chains increase the need for:

- ***On site audit***
- ***Supply chain verification***

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ADULTERATION OF A MATERIAL IS MORE LIKELY IF:

- Expensive material
- In short supply
- **A material tested by non-specific methods**
- Unknown supply chain

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SUPPLIER CHANGES CAN CAUSE OTHER QUALITY ISSUES:

- Excipient and API Bioburden varies
- Reactive impurities in common excipients may degrade drugs, e.g.
  - Hydrogen peroxide, other oxidized species
  - Formaldehyde, other aldehydes
  - Formic, other acids
  - Reducing carbohydrates
- Glass Delamination in vials

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DON'T RELY ON MARKETING LITERATURE

I audited a "GMP" chemical supplier based in the U.S., found:

- Repackage chemicals and API's sourced from brokers and suppliers whom they do not audit.
- "qualify" brokers and suppliers by questionnaires
- One time verification of Certificate of Analysis of two or 3 items from brokers, other items not ever verified
- **Nobody tested glycerin "USP" for absence of DEG, but C of A stated it passed the USP tests which include a test for DEG**
- No change control agreements with their brokers
- U.S. company name and address on package convey an image of first world quality, but contents could come from anywhere

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FDA REGULATORY RESPONSES TO SUPPLY CHAIN ISSUES:

- Guidance Testing of Glycerin for Diethylene Glycol 2007
- Guidance Pharmaceutical Components at Risk for Melamine Contamination 2009
- FDA "Pathway to Global Product Safety and Quality" 2011 signaled future regulatory approach.
- New FDA Office of Drug Security, Integrity and Recalls (ODSIR), includes Division of Import Operations and Recalls and Division of Supply Chain Integrity
- **FDA Safety and Innovation Act, July 2012 "FDASIA"**

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CURRENT FDA REGULATIONS:

21CFR.211 no specific mention of audits or Quality Agreements, has general requirements for Supplier Quality.

21CFR.211.22 Responsibilities of quality control unit. (a) The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company. (d) The responsibilities and procedures must be in writing

21CFR606 - Current GMP For Blood And Blood Components extensive requirements re donor screening and records

21CFR680.1 Sec. 680.1 Allergenic Products. (c) Listing of source materials and suppliers. Manufacturer must list with CBER the name and address of each of the manufacturer's source material suppliers.

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FDA PHARMACEUTICAL COMPONENTS AT RISK FOR MELAMINE CONTAMINATION GUIDANCE, 2009

- Requires drug product manufacturers to determine if components used are at risk for melamine contamination
  - If at risk, recommends testing for melamine
  - Substances at risk include commonly used materials such as albumin, ammonium salts, calcium pantothenate, caseinate, copovidone, crospovidone, gelatin, guar gum, lactose, povidone etc.

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FDA PHARMACEUTICAL COMPONENTS AT RISK FOR MELAMINE CONTAMINATION GUIDANCE, continued

Manufacturers need to know and monitor their supply chain for at-risk components.

- Need to know the **identity and role of the actual manufacturer** of at-risk components
- Need to know the **identity and role of any repackers and distributors** who handle the components before receipt by drug manufacturer.
- Drug Manufacturers get certification from the manufacturer that components are tested for the absence of melamine
- Need to **audit** component suppliers for cGMP compliance.

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FDA TESTING OF GLYCERIN FOR DIETHYLENE GLYCOL GUIDANCE, 2007

- similar expectations

– Drug product manufacturers should do a specific identity test that includes a limit test for DEG on all containers of all lots of glycerin before use

– Drug product manufacturers should know their supply chain for glycerin i.e., the actual manufacturer and any repackers and distributors.

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FDA SAFETY AND INNOVATION ACT,

JULY 2012

"FDASIA"

http://www.gpo.gov/fdsys/pkg/BILLS-112s3187enr/pdf/BILLS-112s3187enr.pdf

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FDASIA SEC. 703. IDENTIFICATION OF DRUG EXCIPIENT INFORMATION WITH PRODUCT LISTING

Section 510(j) (21 U.S.C. 360(j)) amended by **adding** at the end the following: S. 3187 —74: (E) in the case of a drug contained in the applicable list.

Name and place of business of each manufacturer of an excipient in a listed drug, including all establishments used in the production of excipient, facility identifier of establishment, point of contact e-mail address for each excipient manufacturer

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FDASIA SEC. 711. ENHANCING THE SAFETY AND QUALITY OF THE DRUG SUPPLY,

Section 501 (21 U.S.C. 351) amended by **adding** ‘ ‘For purposes of paragraph (a)(2)(B), the term

cGMP includes the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products.

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FDASIA SEC. 714. REGISTRATION OF COMMERCIAL IMPORTERS of drugs effective 2015

Presumably includes brokers, presumably covers the broad FD&C definition of a drug, which includes components (raw materials) of drugs

FDA will develop an Electronic System for Registration and Listing

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INTERNATIONAL REGULATORY RESPONSES TO SUPPLY CHAIN ISSUES:

- **ICH Guidances Q7, Q9, Q10**
- Pharmaceutical Regulatory Inspection Cooperation Scheme (PIC/S) – (43 countries and pharmaceutical inspection authorities, including Europe, FDA)
- **European Falsified Medicinal Products Directive, 2011**
- **Revision to GMP EudraLex Vol 4 Chap 5 production (re supply chain) 2011**
- **European Guidelines March 2013 on Good Distribution Practice of Medicinal Products for Human Use**

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ICH Q7 GUIDANCE FOR API'S 2001:

AGENTS, BROKERS, TRADERS, DISTRIBUTORS, REPACKERS, AND RELABELLERS

- Should comply with GMP as defined in Q7 Guidance, have effective quality management system
- Should maintain complete traceability of APIs and intermediates

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ICH Q7 FOR API'S GUIDANCE:

AGENTS, BROKERS, TRADERS, DISTRIBUTORS, REPACKERS, AND RELABELLERS must retain API traceability documentation:

- Identity and Address of original manufacturer
- Purchase orders
- Bills of lading (transportation documentation)
- Receipt documents
- Name or designation of API or intermediate
- Manufacturer's batch number
- Transportation and distribution records
- All authentic Certificates of Analysis, including those of the original manufacturer
- Retest or expiry date

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ICH Q9 QUALITY RISK MANAGEMENT GUIDANCE 2006.

Recommends Quality Risk Management as Part of Materials Management, to assess & evaluate suppliers & contract manufacturers

- Prioritize which suppliers to audit
- Give most attention to highest risk suppliers
- Define frequency and scope of audits
- Risk Assessment taking into account factors such as:
  - Overall compliance status, history, robustness of a company's quality risk management activities
  - Complexity of the site, manufacturing process, product
  - Results of previous audits/inspections
  - Experience

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ICH Q10 PHARMACEUTICAL QUALITY SYSTEM GUIDANCE 2009

Management of Outsourced Activities and Purchased Materials

- company is responsible to assure the control of outsourced activities and quality of purchased materials.

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ICH Q10 PHARMACEUTICAL QUALITY SYSTEM GUIDANCE 2009

Supplier quality processes should incorporate quality risk management and include:

- Assess prior to outsourcing operations or selecting material suppliers, suitability and competence of supplier to carry out the activity or provide the material using a defined supply chain (e.g., audits, material evaluations, qualification)
- Define responsibilities and communication for quality-related activities.
- Outsourced activities, responsibilities and communication in a written agreement between contract giver and acceptor

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ICH Q10 PHARMACEUTICAL QUALITY SYSTEM GUIDANCE 2009

Pharma Company's Supplier Quality processes should include:

- Monitor and review performance of the contract acceptor or material quality from supplier
  - Identification and implementation of any needed improvements
- Monitor incoming ingredients and materials to **ensure they are from approved sources using the agreed supply chain.**

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EU DIRECTIVE PREVENTION OF THE ENTRY INTO THE LEGAL SUPPLY CHAIN OF FALSIFIED MEDICINAL PRODUCTS (2011/62/EU 8 JUNE 2011)

The Directive applies to all manufacturers, distributors and brokers of medicinal products, API's and excipients ("actors")

- **All actors must register**
- **All subject to inspection**
- **An "actor" must verify that its supplier complies with requirements for registration with the Member State**

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FALSIFIED MEDICINAL PRODUCTS DIRECTIVE

continued

- **Member States must put Directive requirements into legislation & implement by 2013**
- **Legislation must address all manufacturers and all actors in the supply chain**
- **Member States must ensure that manufacture, import and distribution on their territory of active substances, including for export, comply with GMP and GDP for active substances**

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FALSIFIED MEDICINAL PRODUCTS DIRECTIVE

continued

Brokers definition: involved in the sale or purchase of medicinal products without selling or purchasing those products themselves, and without owning and physically handling the medicinal products.

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FALSIFIED MEDICINAL PRODUCTS DIRECTIVE

continued

Defines a Falsified medicinal product as any medicinal product with a false representation of:

- **Identity**
- **Source**
- **History**

This definition does not include unintentional quality defects

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FALSIFIED MEDICINAL PRODUCTS DIRECTIVE

continued

- **Manufacturer** of a medicinal product must conduct **on site audits of both manufacturers and distributors of active substances** for GMP's / GDP compliance
  - Written Certification of Compliance by the Marketing Authorization Holder must show dates of the audits
  - MAA holder must ensure excipients are suitable for use, ensure GMP's applied
  - **verify that the manufacturers, importers or distributors from whom he obtains an API, are registered in their Member State**

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FALSIFIED MEDICINAL PRODUCTS DIRECTIVE

continued

If Manufacturer obtains API's from outside the European Union, can only source from a **country with Equivalent Regulatory Control to the EU, effective 2 July 2013.**

- the "third" country must verify GMP compliance for the manufacturer and provide certification.

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FALSIFIED MEDICINAL PRODUCTS DIRECTIVE

continued

EU Commission will publish list of countries with Equivalent Regulatory Control to EU (after voluntary assessment)

- Switzerland is listed, U.S.A. is being assessed
- Active substances manufactured in listed countries do not require a written confirmation
- EU Commission will regularly verify a country's compliance, first verification 3 years after listing

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GMP EUDRALEX VOL 4 CHAP 5 PRODUCTION, REVISION RE SUPPLY CHAIN, 2011

Changes cont:

- Purchase of starting materials controlled by written procedures
- **Supply chain** of each starting material known & documented
- Specifications established by the manufacturer for starting materials should be discussed with the suppliers

* EU: starting materials include all substances used in production of medicinal product, excluding packaging materials, not just the limited ICH Q7 API context

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GMP EUDRALEX VOL 4 CHAP 5 PRODUCTION, REVISION RE SUPPLY CHAIN, 2011

- Selection, qualification and approval of suppliers, and the purchase of starting materials by staff with a particular and **thorough knowledge of the suppliers and the associated risks involved in that starting material's supply chain**.
- Procedures for assessment, purchase and acceptance of starting materials and critical packaging materials should be documented as part of quality management system.

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GMP EUDRALEX VOL 4 CHAP 5 PRODUCTION, REVISION RE SUPPLY CHAIN, 2011

- Manufacturing authorization holders must ensure active substances are produced in accordance with GMP
- **Suppliers of active substances and certain excipients considered to be high risk materials** used as starting materials, should be periodically **audited** for GMP compliance and to verify that supply chain **traceability of the starting material** is being maintained

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EUDRALEX VOL 4 CHAP 5 GMP'S FOR PRODUCTION:

- Starting materials should only be purchased from approved suppliers named in the relevant specification and, where possible, directly from the producer.
- The approval of suppliers of starting materials should be controlled by QC and production.

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EU GUIDELINES ON GOOD DISTRIBUTION PRACTICE OF MEDICINAL PRODUCTS FOR HUMAN USE 2013

- Appropriate qualification should be performed prior to any procurement.
- The selection, qualification and approval of suppliers controlled by a standard operating procedure and results documented and periodically rechecked.
- If the medicinal product is obtained through **brokering**, the wholesale distributor must verify that the **broker** is registered and complies with requirements
- Due diligence should be carried out by the distributor when entering a new contract

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EU GUIDELINES ON GOOD DISTRIBUTION PRACTICE OF MEDICINAL PRODUCTS FOR HUMAN USE 2013

- **Wholesale distributors must be authorized, must obtain supplies of medicinal products only from authorized wholesale distributors, or who have manufacturing authorization for the product in question**
- **Wholesale distributor must verify compliance with the principles and guidelines of GDP by any supplying wholesale distributor and whether the supplying distributor holds a wholesale distribution authorization.**
- **Where the medicinal product is obtained from the manufacturer or importer, wholesale, distributors must verify that the manufacturer or importer holds a manufacturing authorization.**
- **Purchase of medicinal products controlled by written procedures.**
- **The supply chain of medicinal products should be known and documented.**

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IT'S A JUNGLE OUT THERE!

We should only use **approved suppliers**!

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NEED TO DEVELOP APPROVED SUPPLIER LIST:

Qualification of a supplier is specific to a particular manufacturing location and for specific materials and manufacturing operations performed at that location

- Actual site of manufacture of chemical or component may be different from site where it is packaged in small quantities for customer
- **Need to qualify each supplier location you use**

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APPROVED SUPPLIER LIST

For API's, excipients, complex and at risk materials and components, need detailed Supply Chain info. for all establishments used in their production:

- ***Actual*** manufacturer name and site address
- **Activity** performed at each site (locations for Manufacturing/ Packaging/ Repackaging, Testing)
- Facility identifier of each establishment
- Point of contact e-mail address for each manufacturer
- Who the distributor is, their role, contact person

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APPROVED SUPPLIER LIST TAKES ENORMOUS EFFORT

A small drug development company has hundreds of materials and suppliers to evaluate

A large pharma company has thousands of materials and suppliers to evaluate

Excipient manufacturers sometimes refuse audits, especially by small customers

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APPROVED SUPPLIER LIST

Must show for each material and supplier combination:

- **Result of Risk Assessment**
- **Supplier and Material Qualification Plan with action items/completion date:**
  - Whether and how often to audit
  - Registration in supplier's change notification program
  - Signed Quality/Technical Agreement
  - TSE/BSE/Certificates of Origin
  - European Directive for Quality of Medicine (EDQM) certificate
  - etc.
- **Date of Approval**

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APPROVED SUPPLIER LIST TAKES ENORMOUS EFFORT

Supplier qualification is multifaceted and difficult

- *Need to apply resources where most needed:*
- **Prioritize by Risk Assessment for each material and supplier combination!**

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AUDIT MEDIUM TO HIGH RISK MATERIALS SUPPLIERS

- **Reduce effort by using Shared Audits for commodity materials** (raw materials, excipients and common API's, not custom manufactured)
  - **Glycerin, materials at risk for melamine contamination, heparin etc. are medium / high risk commodity materials**

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FOR LOW TO MEDIUM RISK RAW MATERIALS

- **If you use materials verified or certified by independent Third Party** e.g. **IPEC, ExciPact™ or USP, you may not need to audit**
- **If low risk you could do Supplier evaluation instead of audit**
  - e.g. for non product contact components like sample containers, media for micro testing if you do QC testing of each batch

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SHARED AUDITS

THIRD PARTY AUDITS ARE ACCEPTED BY EMA, FDA

if *relevant* and *no conflict of interest*

See http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000027.jsp#section1

- Audit & report must relate to a particular supplier facility and to materials made at that facility that are used by the drug or device manufacturer
- The audit and report need to be recent
- Audit commissioned by customer not manufacturer
- Auditor must not be ex employee/consultant of manufacturer

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SHARED AUDITS

IPEA

International Pharmaceutical Excipients Auditing, Inc., subsidiary of IPEC-America

IPEA Certification of Conformance Excipient GMP

- Supplier pays $22,000 initially, then $11,000 pa
- 6 Excipient GMP Conformance Certification Audit Reports, $750 each

- 9 shared Audit reports available for $1500 each
- $5500 if Sponsor requests a new audit, to be shared

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SHARED AUDITS

Rx-360 (International Supply Chain consortium) Joint Audits program started 2012

- members include 26 Drug Product manufacturers, 31 suppliers, 24 others
  - 35 Audit reports available
    - 33 API's
    - 57 raw materials, excipients, vials, packaging
    - 2 chromatography resins,
    - $5000 for report /$2500 for a member

Membership fees $30,000 /year for manufacturers, $6,000 /yr for suppliers

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SHARED AUDITS - In Europe:

- **APIC**, Active Pharmaceutical Ingredients Committee, (Sector Group within CEFIC / European Chemical Industry Council)
  - 2 Audits reports (Boehringer Ingelheim 2012, Excella GmbH 2012),1500 €
- **QP Association Shared Audits Database**, only for members
  - http://www.qp-association.eu/qpag_publications_008.html
- **VfA in Germany** (Verband forschender Arzneimittelhersteller / Research based pharmaceutical companies) 20 members
- **AFA Asociacion Forum Auditorias** founded by pharmaceutical companies in Spain, performs joint audits globally

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VERIFIED OR CERTIFIED

- **EXCiPACT™** Independent 3rd party certification of manufacturers, suppliers and distributors of pharmaceutical excipients worldwide

- **USP Verified Pharmaceutical Ingredients Program**

http://www.usp.org/usp-verification-services/usp-verified-pharmaceutical-ingredients/verification-qualification-processes

5 companies from India, China, Turkey, U.S. participate

– 25 API's/ excipients/materials verified so far

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