



Joining efforts !

www.forumauditorias.org

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- Association of Pharmaceutical companies
- AFA provides 3rd party audit services.
- To Pharmaceutical Companies worldwide (more than 70 companies).
- AFA activity allows to figure out the GMP audit to the suppliers (API, Excipients, packaging, lab services, logistics, ...)

- *ALCALA FARMA*
- ALCON
- AMGROS
- ASAC PHARMA
- AUDEN MCKENZIE
- BAXTER AG
- BELLS HEALTHCARE
- BIMEDA
- BIOTRONIK
- *BOEHRINGER INGELHEIM GROUP*
- CASEN FLEET
- CHEFARO UK LIMITED
- COMBINO PHARM
- CONTRACT PHARMACAL CORP.
- CROSS VETPHARM
- Dr. TORRENS
- DSM PHARMACEUTICALS
- *FAES FARMA*
- FARMALIDER
- FERRER INTERNACIONAL
- FRESENIUS KABI ESPAÑA
- GENESIS PHARMACEUTICALS LTD.
- GES PHARMA
- HENNIG AG
- INTRAPHARM LABORATORIOS
- J. URIACH & CIA GROUP
- KERN PHARMA
- LAB ESTEDI
- LAB LESVI
- LAB. ALMIRALL
- LAB. ALTER
- LAB. DR. ESTEVE
- LAB. ERN
- LAB. FELTOR
- *LAB. INIBSA*
- LAB. LEON FARMA (CHEMO GROUP)
- LAB. LETI
- *LAB. MEDICAMENTOS INTERNACIONALES (GRUNENTHAL GROUP)*
- LAB. MENARINI
- LAB. PÉREZ GIMÉNEZ
- LAB. REIG JOFRE
- LAB. RUBIO
- LAB. SEID
- LAB. SERRA PAMIES
- LAB. VIÑAS
- LABIANA
- LABORATORIOS SALVAT
- LACER
- LAINCO
- MARTINEZ LLENAS
- Mc NEIL
- MERCK GROUP
- MYLAN
- NUVO RESEARCH
- OMEGA PHARMA
- PINEWOOD
- RECIPHARM
- RIVOPHARM
- SANTEN OY
- SYNTHON HISPANIA
- TEVA PHARMA
- VIMINCO
- WARNER CHILCOTT
- WELDING
- WILLIAM RANSOM & SON PLC

■ : AFFILIATES



HEALTH AUTHORITIES

REGULATORS



AUDITORS

*AFA CERTIFIED
AUDITORS*



SUPPLIERS
MANUFACTURER

QUALIFIED PERSONS

*MANUFACTURING
AUTHORIZATION HOLDERS*



NEW AUDITS

New audits sponsored by the affiliates and costumers

TRAINING & COMPLIANCE SUPPORT

AFA provides training and compliance support to costumers

AUDITS IN DATA BASE

More than 250 audits in the AFA data base are available for Pharmaceutical companies
(under permission of audited companies)

Benefits

HEALTH AUTHORITIES

- Achievement of the safety goals
- Spreading and easing compliance to small companies

PHARMA COMPANIES

- Quality and Scientific Approach
- Confidentiality
- The highest Quality / Cost Rate
- Quick response & Flexibility
- Infrastructure in China

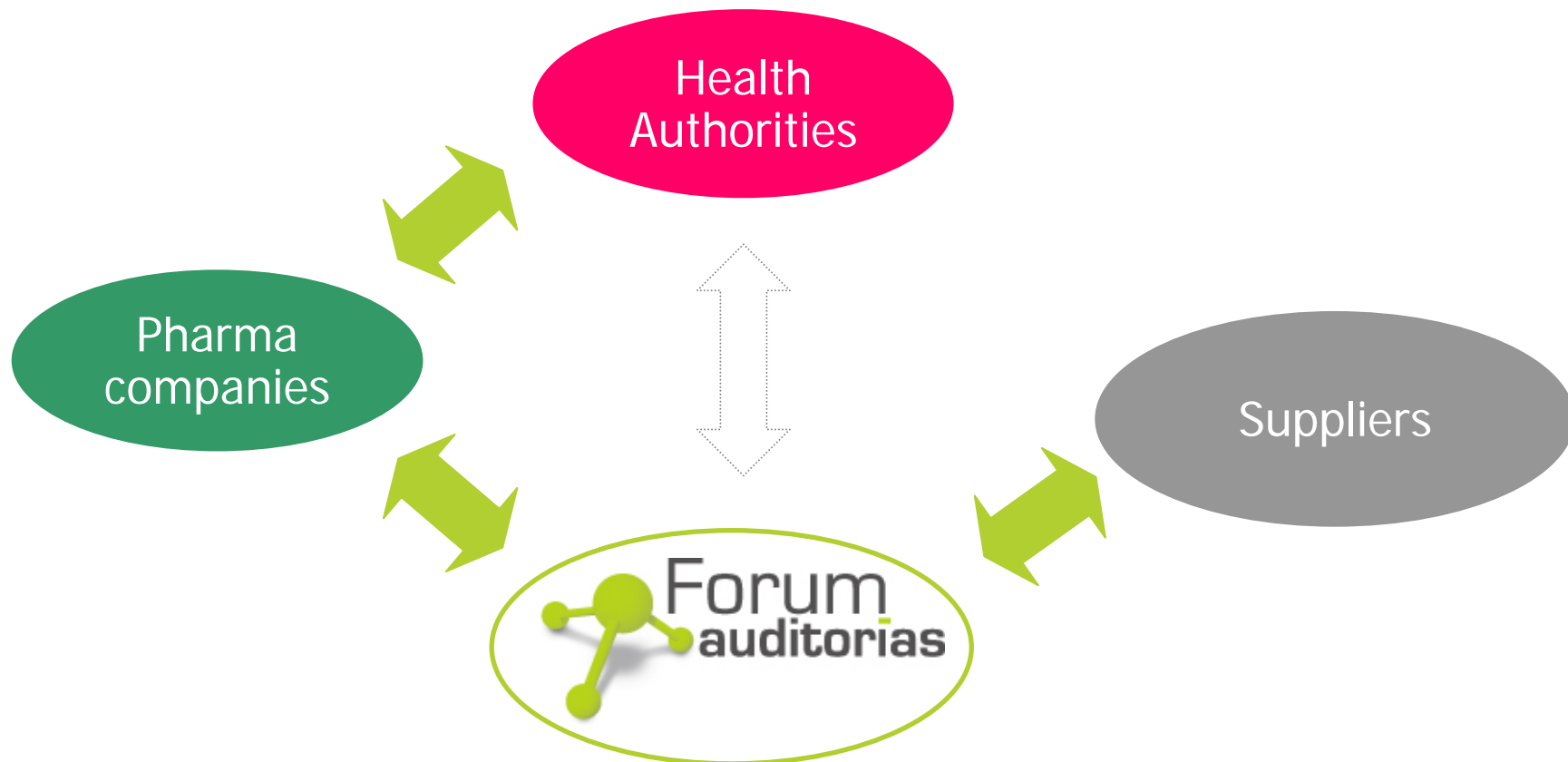
SUPPLIERS

- Audit approach focused in real risk
- Confidentiality
- GMP Audit Certificate
- **Future audits request could be derived to AFA, avoiding new audits**
- Less audits-less costs

Win-Win solution !



It's a Win-Win solution for all parties!!



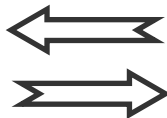
PHARMACEUTICAL
COMPANIES

AUDIT REQUEST

*Intercompany
Protocol*

Audit. Request

AFA
QUALIFIED
AUDITORS



Audit Report



OPTIMIZATION PROCESS

- Selection of auditors
- Setting up acceptance criteria and agenda
- Reviewing the audit reports
- Information safely maintained - **CONFIDENTIALITY**

AFA REPORT

CORRECTIVE PLAN FOLLOW-UP

PHARMACEUTICAL
COMPANIES



- **AFA QUALIFIED AUDITORS**
 - Profile meets the Intercompany Protocol requirements
 - AFA Training Program
 - Co-auditor in several audits
 - Approval by the AFA board
- **ABSENCE OF CONFLICT OF INTEREST WITH THE AUDITED COMPANY**
- **CONFIDENTIALITY AGREEMENT**

IT'S NOT A "NICE TO HAVE" PROJECT

IT'S WORKING SINCE 2005 !!

70 companies benefit of AFA services

More than **300** audits performed around the world

- 65% API
- 15% EXCIPIENTS
- 10% PACKAGING
- 7% ANALYTICAL LAB
- 3% OTHERS

- **2004:** Agreement on the rules → Intercompany Protocol
- **2004 – 2005:** 11 audits (pilot plan). AFA goes live.
- **2006:** 25 audits
- **2007:** 65 audits
- **2008:** 70 audits
- **2009:** 70 audits
- **2010:** 80 audits performed
- **2011:** 90 audits programmed

