PQE

COMPLETE QUALITY SOLUTION
FOR THE LIFE SCIENCE INDUSTRY

PQE'S APPROACH TO ICH Q3D

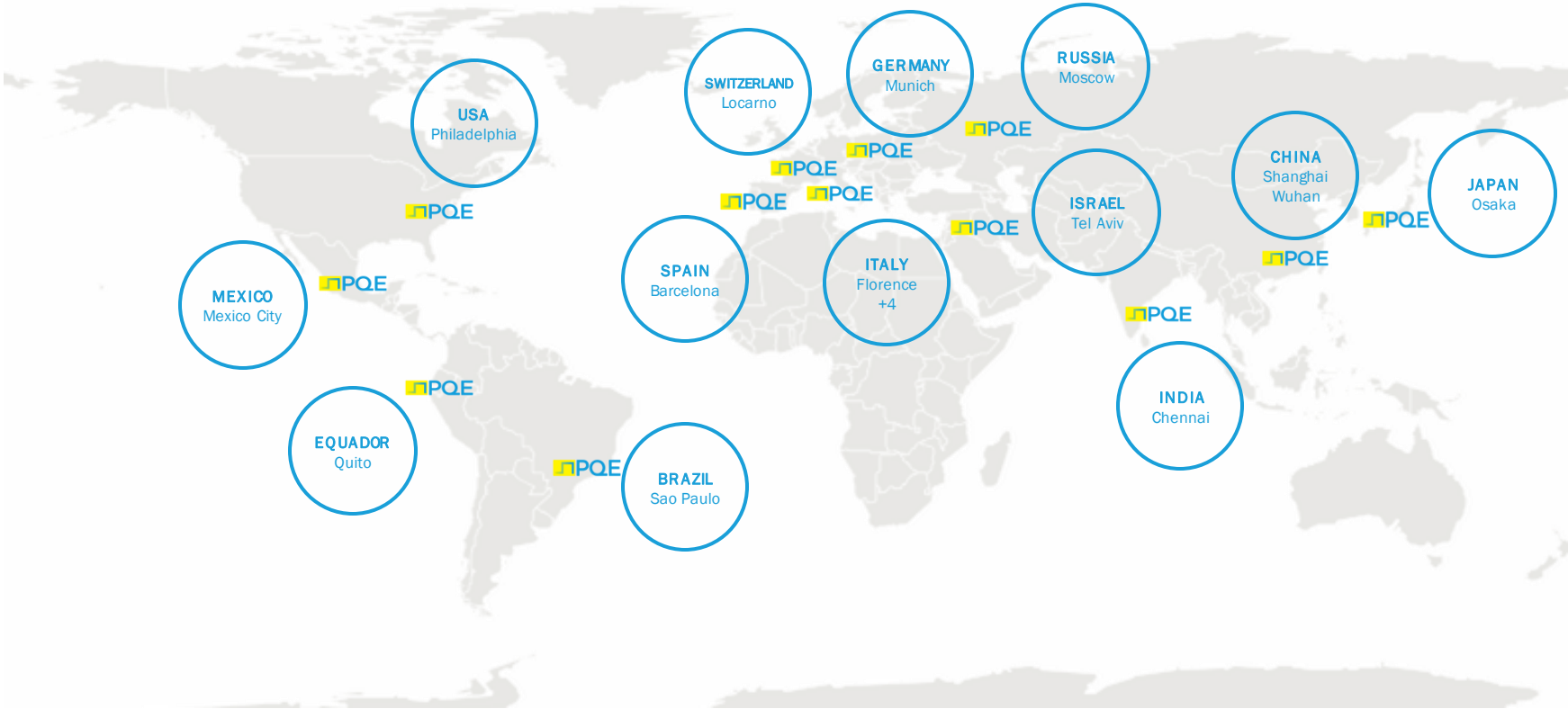
FAST FACTS 1/2

- Complete Quality Solution Provider For Life Science Industry Since 1998
- Global Presence , 18 Offices From US To Japan
- +500 Consultants Permanently Employeed On Board
- Continuous Growth Of Revenues And Resources From 2010
- 25 Languages Spoken Inside The Company Including Russian, Arabic, Chinese And Japanese

FAST FACTS 2/2

- One Of The Few Companies Providing Deliverables And Solutions And Not Just Man Power
- Successful Track-record In Remediation Project
- Certified ISO 9001 Since 2002
- Active Projects In 48 Countries
- Active Collaboration With Regulatory Agencies
- One Of The Few Companies Able To Provide Full Support In Case Of FDA WL Both In Medical Device And Pharma Fields

LOCATIONS


USA
Philadelphia
SWITZERLAND
Locarno
GERMANY
Munich
RUSSIA
Moscow
CHINA
Shanghai
Wuhan
JAPAN
Osaka
ISRAEL
Tel Aviv
MEXICO
Mexico City
SPAIN
Barcelona
ITALY
Florence
+4
INDIA
Chennai
EQUADOR
Quito
BRAZIL
Sao Paulo

SELECTED REFERENCES - PHARMA

- ALLERGAN
- BAYER
- BAXALTA
- BAXTER
- BERLIN CHEMIE
- BIOCLON-SILANES
- BIOTON
- BOEHRINGER INGELHEIM
- BRACCO
- CHEMO
- F.I.S.
- FAREVA - IDA
- FRESENIUS
- GALDERMA (NESTLE)
- GENEPHARM
- GSK
- HAILING
- HELSINN
- HOSPIRA
- IDT
- INFA
- INTI
- J&J - JANSSEN
- JIUZHOU
- KAMADA
- KEDRION
- LABORATORIOS PISA
- LAVIFARM
- MERCK SERONO
- MICRO MACINAZIONE
- NOVARTIS
- OPTONOL
- PFIZER
- PERRIGO
- PROCAPS
- REIGJOFFRE
- SANDOZ
- SANOVEL
- SANOFI
- STADA
- TAKEDA
- TEVA/TAPI
- TRIFARMA
- VALEANT
- ☐ *...AND MORE...*

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INTRODUCTION

- New drug products submitted for approval in Europe must comply with the new ICH Q3D Guidelines for Elemental Impurities in June 2016
- Existing products must comply in December 2017
- The new guideline states that the manufacturer of the drug product/Marketing Authorisation Holder (MAH) should base his control strategy for elemental impurities on a risk assessment which is part of an overall risk management of the potential presence for such impurities to occur in the product.

- Drug Product Approach:

The manufacturer will scan batches of the drug product for the presence of any elemental impurities to be able to do a risk assessment to support risk management and to justify a control strategy. Where necessary the control strategy will include specification(s) to the drug product tested by a validated analytical approach. Analytical data only, without a risk assessment, will not be sufficient and the justification to omit a routine control will with this approach have to be more extensive than just data from a few batches

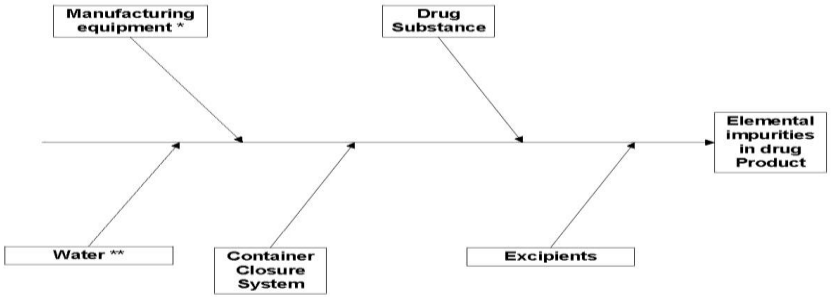
Component Approach

With this preferred approach, the contribution of elemental impurities from each component is assessed and summarized and the combined contribution of an element is compared with the PDE in the risk assessment and if necessary handled in the subsequent risk management and the establishment of a control strategy. In the European context the conditions for a drug product manufacturer to do the risk assessment may differ depending on the origin of the component.

PQE'S APPROACH TO ICH Q3D

The risk assessment process can be summarized in the following steps:

1. identify known and potential sources of elemental impurities (EI) that may be found in the drug product



2. evaluate the presence of particular EI in the drug product which may come from the contamination by the active ingredient, excipients, process equipment and packaging materials
3. identify if controls built into the process are sufficient or identify additional controls to be considered in order to limit elemental impurities in the drug product (i.e. the potential elemental impurity should not exceed the PDE)

DOCUMENTS REQUESTED

- Product composition (active ingredients, excipients, packaging materials)
- Manufacturers / suppliers of each active ingredient, excipient, packaging material
- Manufacturing process description, with details on process conditions, and process flow-chart
- Description of involved equipment in each process stage
- Analysis made on elemental impurities at any process stage, starting from each component, going through IPCs and intermediates until the final release of the drug product

PQE'S RESOURCES CAPACITY FOR ICH Q3D

Thanks to PQE's worldwide office, for this kind of activity PQE is able to involve a big number of resources. On request, PQE can provide all the related CVs.

This could allow to manage a high number of products in parallel.

www.pqe.eu

PQE

info@pqe.eu