Areas of discussion

- Supply chain complexity and traceability

- New product introduction

- Quality

- Compliance

- Regulatory supervision

Supply chain complexity

- Supply chains cross borders and continents

- Complex

- Working with suppliers:

    - Quality / Technical Agreements

    - Audit program

    - QC Testing

    - Trust & relationship management

Supply Chain Mapping

- New text in Chapter 5 of EU GMP Guide (for medicinal product manufacturers):

  - The supply chain and traceability records for each active substance (including active substance starting materials) should be available and be retained by the EEA based manufacturer or importer of the medicinal product

- This requires (a) supply chain mapping and (b) a demonstration of transparency from the API manufacturer, back to the active substance starting material

New Product Introduction

- Risk based application prior to introduction

- Sound, modern scientific approach

- Dedicated or non-dedicated facility

- Recent EU Guideline
  Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities (EMA/CHMP/CVMP/SWP/169430/2012)

Guideline

- *While APIs are not discussed in Chapters 3 and 5 of the GMP Guideline, the general principles outlined in this guideline to derive a threshold value for risk identification could be applied where required.*

- New science and
  new guidance beyond ICH Q7
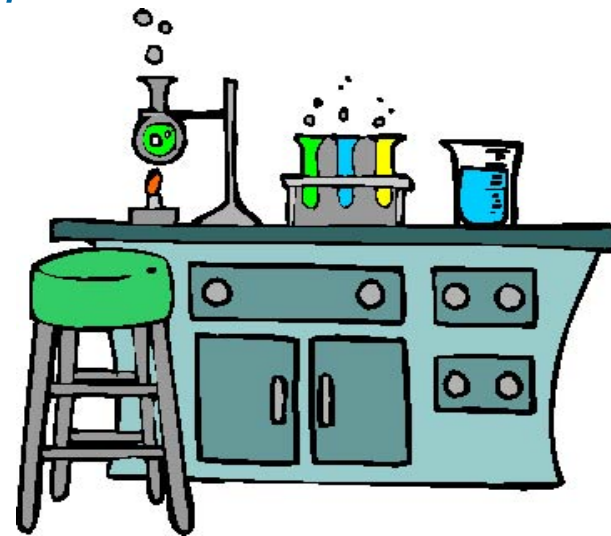
Quality

- Quality is a cultural mindset

- Requires a belief that quality is in everybody's role

- Integrated working across departments

- Training

- Think of ways that you can measure the quality culture?

Compliance

- Understanding of GMPs

  - Training sessions on Q&A are useful
    (so make the most of this training session!)

  - Compliance beyond ICH Q7

  - Other parts of the PIC/S GMP Guide are relevant e.g. Annex 2

- Export of APIs into European Union and the Falsified Medicines Directive (2011/62/EC)

Falsified Medicines Directive

- Each batch of API accompanied by '*written confirmation*'

- Listed countries (January 2015):

  - Switzerland, Australia, USA & Japan

- See presentation from European Commission

Regulatory Supervision

- Multiple repeat inspections from Agencies is time consuming

- Encourage the use of PIC/S network for exchange of inspection reports to offset multiple inspections

- Sharing of information: PIC/S allows for a more effective use of inspection resources through the voluntary sharing of GMP inspections reports. Membership is also a cost-saving measure for the inspection authorities confronted with an increase of inspections, notably in the field of active pharmaceutical ingredients (APIs).
  http://www.picscheme.org/benefits.php

Inspections /audits

- Preparation is key

- Well constructed documentation e.g. Site Master File, Product Quality Reviews etc.

- Transparency and Traceability

Final thoughts

- The world is getting smaller

- Companies need to grasp new and emerging GxPs

- Proactive rather than reactive

- Better engagement with Companies & Regulatory Agencies

- Harmonisation and sharing amongst PIC/S Agencies

Conclusion / Questions

- Why do I have to do that…..?

- How can I do that better?