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Quality Risk Management

of the GDP Supply Chain

Crowne Plaza Hotel, 25/2/2010

Dr Cormac Dalton
Inspector

Supply Chain Experiment

- Pharmaceutical excipient ordered – 3rd December 09
- Humidity sensitive substance
- Source – Pingyang, China



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Excipient Supply Chain

- 5th December 09 – Pingyang to Wenzhou (55km)
- 7th December 09 – Wenzhou to Shanghai (364km)
- 14th December 09 – Arrives Portlaoise, Co. Laois
- 15th December 09 – Arrives Kilbarrack, Co. Dublin
- 16th December 09 – Arrives at final destination
- Limited testing performed – complies with specification



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Christmas Shopping

- Item ordered – 4th December 2009
- Source country = EU
- One order comprised of 4 components
- Delivery arrived intact on 22nd December 2009
- Three correct components plus one incorrect component received



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Purchase of medicinal products online

- Illegal to purchase POMs online

Medicinal Products (Prescription and Control of Supply) Regulations 2003 – 2009

- **Over 50%** of medicines bought online are fake or substandard

(reference *WHO*, 2010)

- <http://www.who.int/mediacentre/factsheets/fs275/en/>



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What complicates the GDP supply chain?

- The Product?
- The Distance travelled?
- The Manufacturer?
- The Storage Facility?
- The Customer?
- Personnel throughout the supply chain?



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What simplifies the GDP supply chain

- **Quality Risk Management**
- By building in **Quality Risk Management** into the supply chain, you can ensure that the wholesaled medicinal product will continue to comply with its **Quality** specifications as detailed in the Marketing Authorisation.



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Supply Chain Management for Manufacturers

- Supply Chains for Manufacturers are typically lengthy
- Many raw materials & raw material suppliers
- Intermediate manufacture is often outsourced
- **Quality Risk Management** can be used effectively to assure the Manufacturer's Supply Chain
- See IMB GMP Information Day 2008
- <http://www.imb.ie/EN/Events/About-Us/GMP-and-Market-Compliance-Information-Day-2008.aspx?categorypageid=0&categorytypeid=-1>



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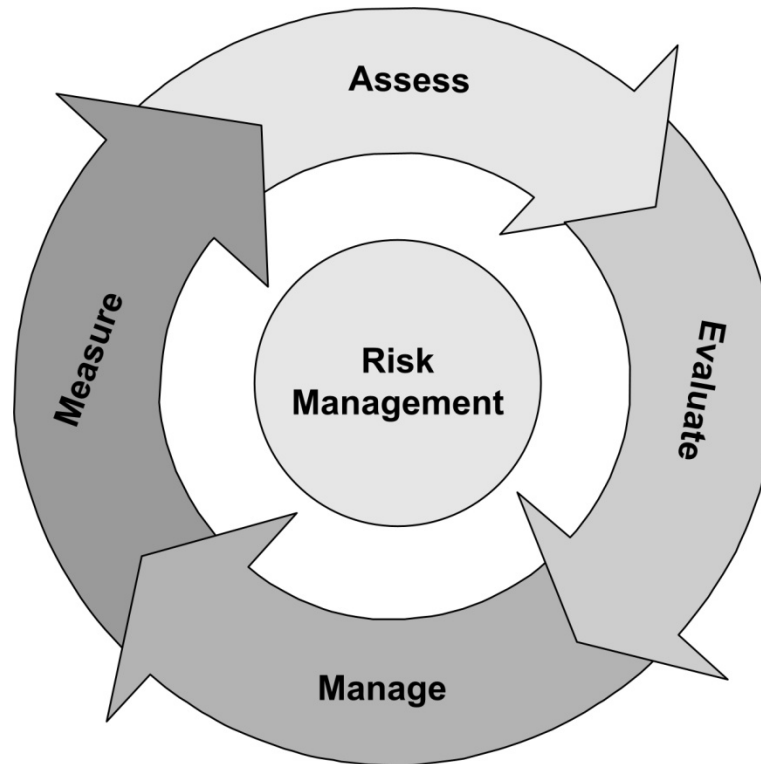
Quality Risk Management for GDP

- Areas where **Quality Risk Management** can be applied are:
 - The Product
 - The Manufacturer
 - The Storage Facility
 - The Customer
 - Personnel



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The flow of Quality Risk Management



- For information on the methodology of QRM, see ICH Q9 document (follow link)
- http://www.ich.org/MediaServer.jsr?@_ID=1957&@_MODE=GLB



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The Product

- What are the temperature / humidity requirements for the product?
- What temperature / humidity is the product exposed to during transit?
- Is a validated controlled temperature / humidity shipment required?
- Are temperature / humidity loggers required with each shipment?
- Where are the risks?



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The Product (continued)

- How are temperature / humidity excursions managed?
- In the case of an excursion, is there involvement with the Marketing Authorisation holder and/or the Manufacturer?
- Do the products fall under specific categories of products with additional requirements e.g. controlled drugs, 'exempt' medicinal products?
- Do you comply with IMB requirements?
- **Where are the risks?**



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The Manufacturer

- Who manufacturers / supplies the finished product?
- Is the manufacturer licenced to manufacture products that you are wholesaling?
- Do you have a copy of the licence and is it accurate and reflective of the products you wholesale?
- How can the primary wholesaler assure themselves that each batch received has been released to market by a Qualified Person (QP)?
- **Where are the risks?**



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The Manufacturer (continued)

- How do you manage complaints and product recalls with the manufacturer?
- Are the roles and responsibilities of the primary wholesaler and the manufacturer clearly defined?
- Is there a technical or quality agreement in place to clarify roles and responsibilities of each party?
- **Where are the risks?**



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The Storage Facility

- What **risks** at the facility can impact the quality of the medicinal product?
 - Temperature / humidity
 - Pest control
 - Cross contamination
 - PA / PL mix-ups
- How do you assure the correct product is distributed to the correct customer?



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The Customer

- Who are your customers?
- How do you maintain 'current' supplier lists?
- How do you assess the entitlement of **new customers** to receive medicinal products?
- How do you assess the entitlement of **existing customers** to continue to receive medicinal products?
- **Where are the risks?**



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Personnel

- What GDP training is provided to your personnel?
- How do they identify risks to the product quality?
- Does your self inspection programme bring about continuous improvement?
- **Where are the risks?**



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Output from a QRM exercise

- Have you identified **potential risks** to product **quality**?
- Have you effectively acted upon potential risks?
- Do you see a reduction in deviations / excursions?
- Do you see a reduction in near misses and product recalls?
- Do you see a reduction in IMB observations on inspection?



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Changes to GDP Operations

- Changes in operations can impact the findings of an initial **Quality Risk Management** exercise
- Consider reassessing such changes and their impact
 - New products
 - New supply routes
 - New manufacturers (suppliers)
 - New storage facility or significant premises changes
 - New customers
 - New personnel throughout the supply chain
- **Quality Risk Management** is a living philosophy



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Effective Quality Risk Management

- Why consider adopting **Quality Risk Management**
 - Provides total traceability of wholesaled products
 - Reduces deviations and non-conformances
 - Streamlines wholesaling activities
 - Reduces the risk of affecting product quality
 - Reduces the risk of product recalls
 - Reduces cost to wholesaling operations



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Effective Quality Risk Management

- Why adopt **Quality Risk Management**
 - Ensures the **Quality** of the Medicinal Product whilst conducting wholesaling activities
 - Negates any impact on product **Safety** & **Efficacy**
 - Negates the risk of falsified medicinal products entering the supply chain
 - **Reduces risks !!**
 - **Protects Public and Animal Health**

Acknowledgments

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