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Best Practices in Wholesale Distribution

Wholesale Distribution Information Day, 25/2/2010

Alfred Hunt
Inspector

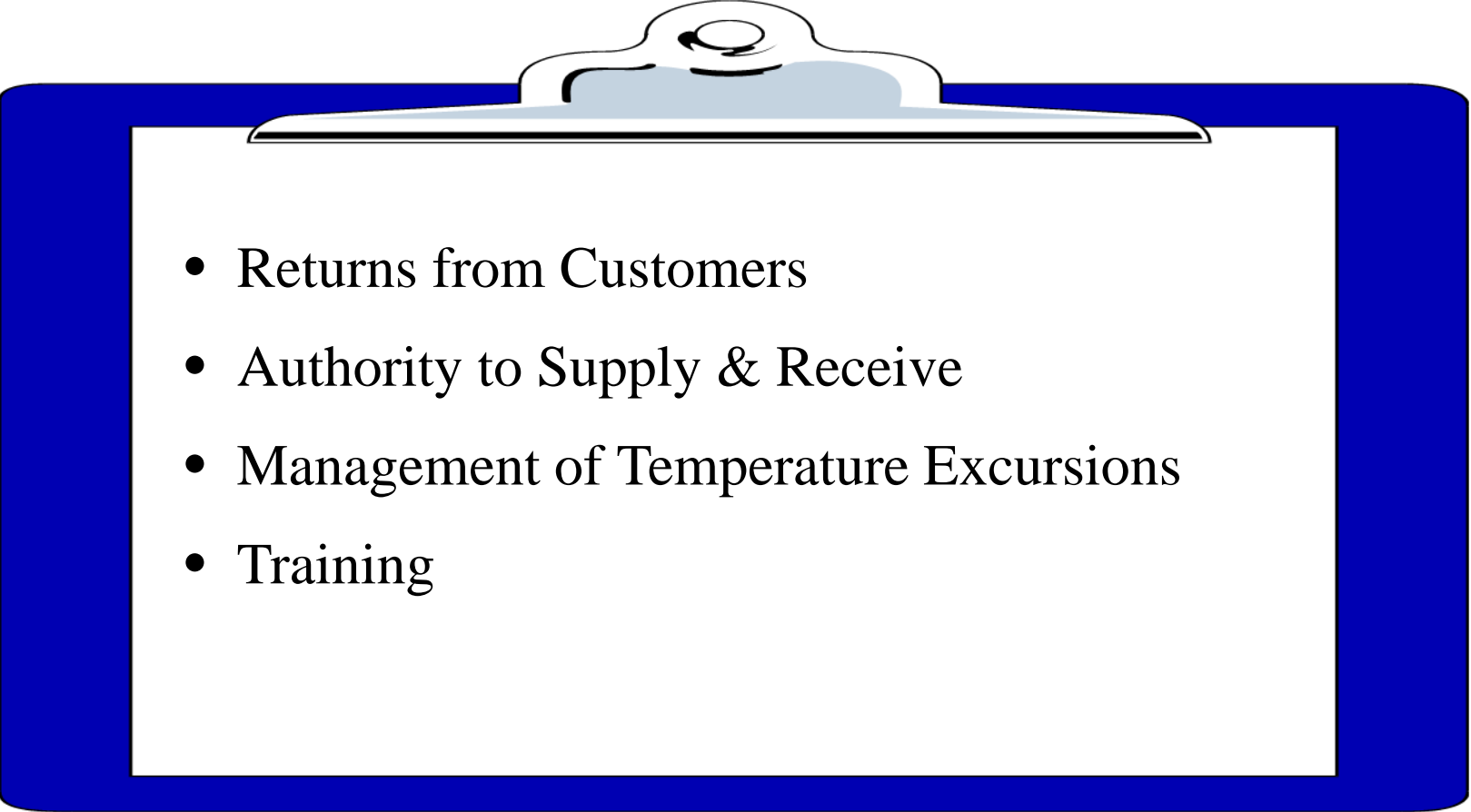
“Imitation is the sincerest form of collective stupidity”

—W. Carroll Munro, Marketing Director, PepsiCo



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Agenda

- 
- Returns from Customers
 - Authority to Supply & Receive
 - Management of Temperature Excursions
 - Training



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Returns

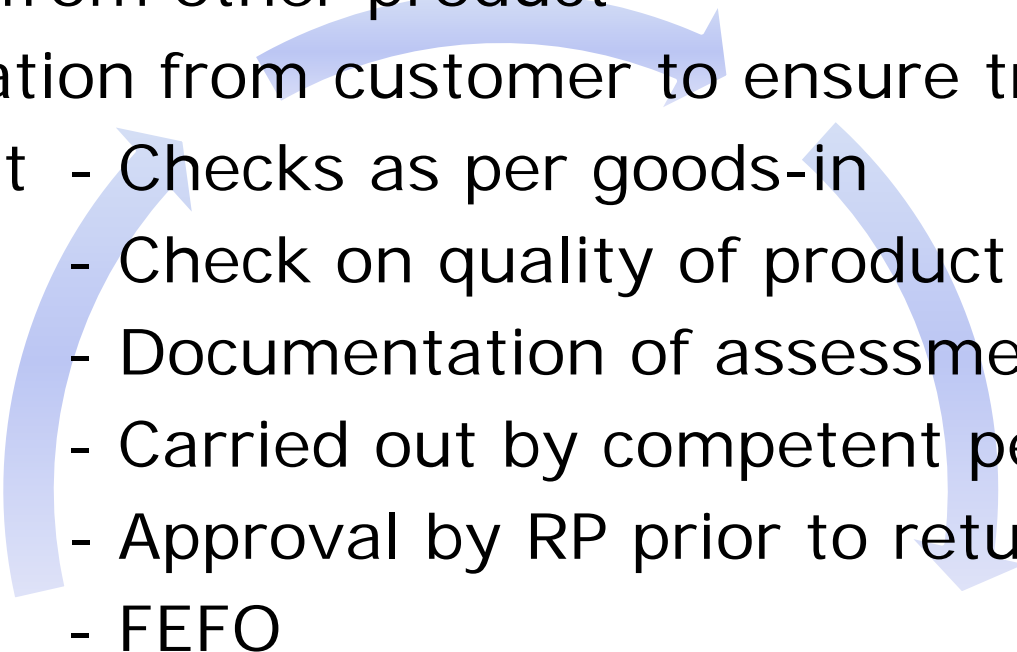
Any product which has left the control of the wholesaler's quality system which is subsequently returned

A commercial issue leading to quality issues



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Returns

- Segregate from other product
 - Documentation from customer to ensure traceability
 - Assessment
 - Checks as per goods-in
 - Check on quality of product
 - Documentation of assessment
 - Carried out by competent person
 - Approval
 - Approval by RP prior to return to stock
 - FEFO
- 



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Returns

- Controlled drugs placed in secure area
- Refrigerated Product – assurance that cold chain has not been broken
- Awareness of potential for counterfeit products entering through returns
- Staff appropriately trained
- Document waste
- Described in a procedure



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Returns

Wholesaler should –

- Manage volumes of returns processed daily
- Use technology available (e.g. weight checking)
- Check as to whether initially supplied (e.g. recording of batch numbers)
- Carry out a risk analysis on returns process – identify areas of focus



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Returns

Wholesaler should –

- Be careful of promoting bonus buys
- Consider collectively adopting a formal policy on how long after delivery a return will be accepted



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Returns

No documentation – no return
+
Not originally supplied – no return
+
Not recently supplied – no return
=
Reduced Returns



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Authority to Supply / Receive – Why?

Wholesaler is responsible for ensuring that suppliers are authorised to supply and customers authorised to receive

- EU GDP Guidelines Paragraph 5

“Orders from wholesalers should be addressed only to persons authorised to supply medicinal products...”

- EU GDP Guidelines Paragraph 17

“Deliveries should be made only to other authorised wholesalers or to persons authorised to supply medicinal products to the public”



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Authority to Supply – How?



- Supply
 - Request a copy of WA / MIA
 - Check categories authorised to supply
 - Check IMB website
 - NB - Controlled Drugs
 - Review carried out by competent person



Question – Who is actually supplying you???



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Authority to Receive– How?



- What category does customer fit into – Wholesaler, Pharmacist, Hospital...?
- What classification of medicinal product are they entitled to receive – general sale, pharmacy confined, cold chain, controlled drugs...?
- What classification of medicinal product are we supplying to them?

Question – How can this be managed???



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Customer Matrix

Customer Type	Customer Code	General Sale	Pharmacy Confined	Prescription Only	Controlled Drugs	Cold Chain	Exempt
Retail Pharmacy	1	✓	✓	✓	✓	✓	✓
Wholesaler GS/P/POM/CD	2	✓	✓	✓	✓		
Wholesaler GS/P/POM/CC	3	✓	✓	✓		✓	
Staff Sales	4	✓					
Joe Bloggs Wholesale		✓	✓	✓			



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Authority to Receive– How?

- How to Apply –
 - Manual System for cross referencing
 - IT System of allowing / blocking sales
or
 - Combination of both

NB: Sales Department must be within Quality System!



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Management of Temperature Excursions

A temperature excursion is a deviation from the labelled storage conditions of a product for any duration of time

All excursions should be investigated to assess possible quality impact on products



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Preventing Temperature Excursions

- Corrective Actions
 - Sky lights / windows
 - Heating / cooling / fans
 - Insertion of curtains on fridges / cold rooms
 - Adjusting set points (re-mapping required!)
 - Maintenance
 - Risk Assessment
 - Self Inspection – Trends?



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Mean Kinetic Temperature (MKT)

$$T_k = \frac{\Delta H / R}{-\ln \frac{e^{-\Delta H / RT_{(1)}} + e^{-\Delta H / RT_{(2)}} + \dots + e^{-\Delta H / RT_{(n)}}}{n}}$$

- Must only be used in agreement with manufacturer / MAH
- May only be used for isolated excursions - Cannot be used to compensate for poor temperature control of storage facilities
- Excursions should be documented and investigated and reported to the MAH



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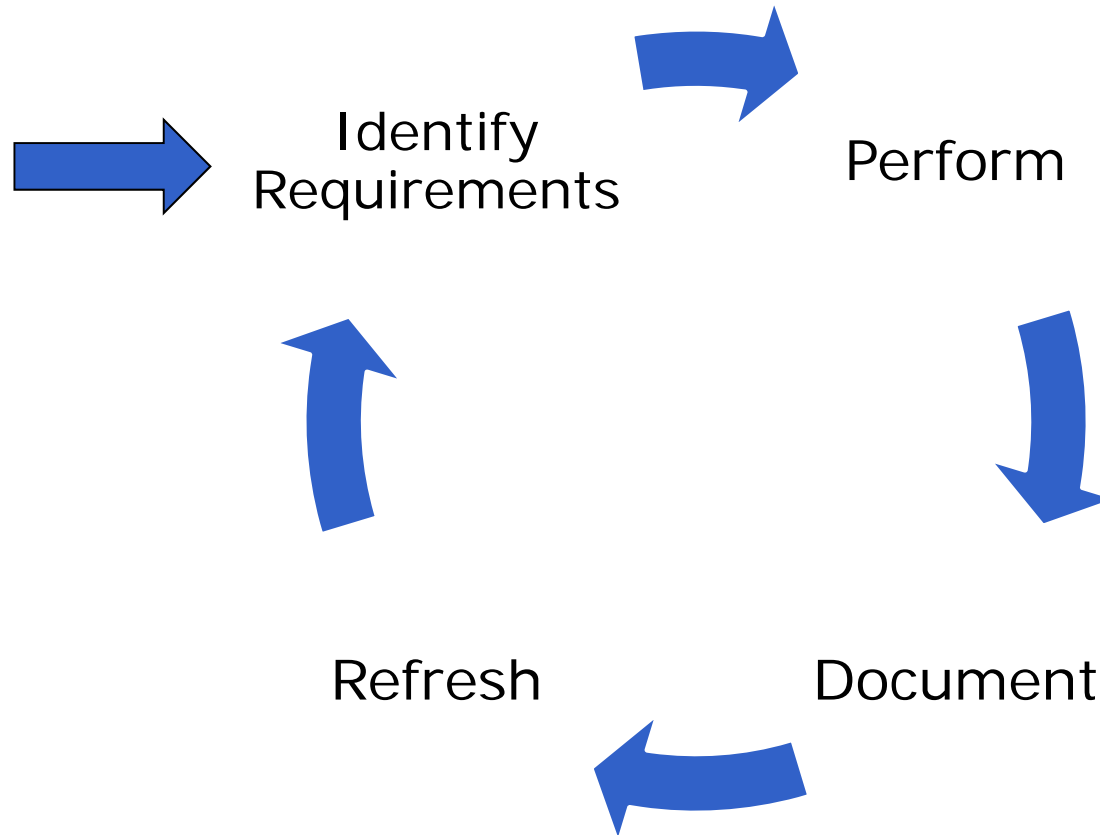
NB!

- All excursions must be investigated and documented
- Must have justification for allowing excursions (e.g. of <1hour, <30°C etc.)



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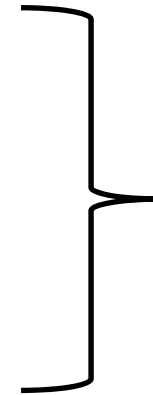
Training



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Training

- Identify
 - Induction training
 - Changing positions
 - New procedures
 - New practices / tasks



Training Plan



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Training

- Perform
 - Method of training - On the job, read & understand...
 - Who performs the training?
 - Duration of training
 - Assessment



Training

- Document
 - SOP number & revision, task
 - Trainee & trainer signature
 - Date
 - Duration
 - Assessment



Training

- Refresh
 - Annual GDP
 - CAPA , Deviations
 - Documentation updates
 - Customer complaints, recalls



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Thank you

alfred.hunt@imb.ie
compliance@imb.ie
www.imb.ie

01-6764971



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