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# Contracted Services

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*Wholesale Distribution Information Day, 25/2/2010*

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Inspector

# Introduction

*Contracted Services* – The delegation by the authorisation holder to a third party of a service which could impact on the quality of a product or on the distribution activity



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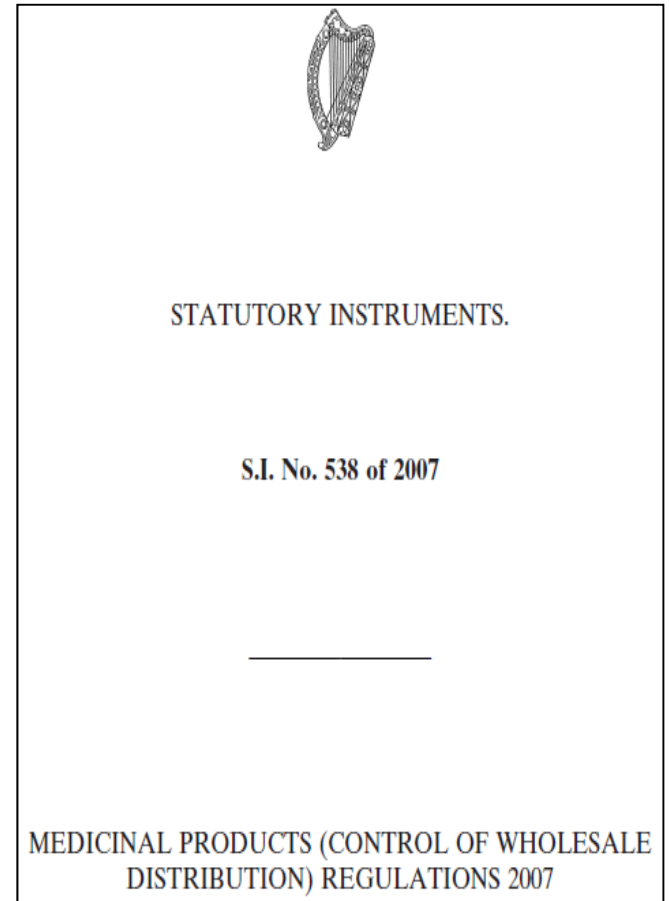
# Topics

- Responsibility for Contracted Services
- Responsible Person Support
- Pest Control
- Security
- Alarm Monitoring
- Waste Management



# Responsibility for Contracted Services

- ***The authorisation holder shall*** provide and maintain such staff, premises, installations, equipment and procedures for the handling, storage and distribution of the medicinal products that he or she handles, stores or distributes under his or her authorisation, as are necessary to avoid deterioration of the products



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# Responsibility for Contracted Services

- Authorisation Holder retains responsibility
  - Ensure suitability
  - Service Level Agreement
  - Procedures
  - Training
  - Maintain oversight
  - Self inspection



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# Responsible Person Support

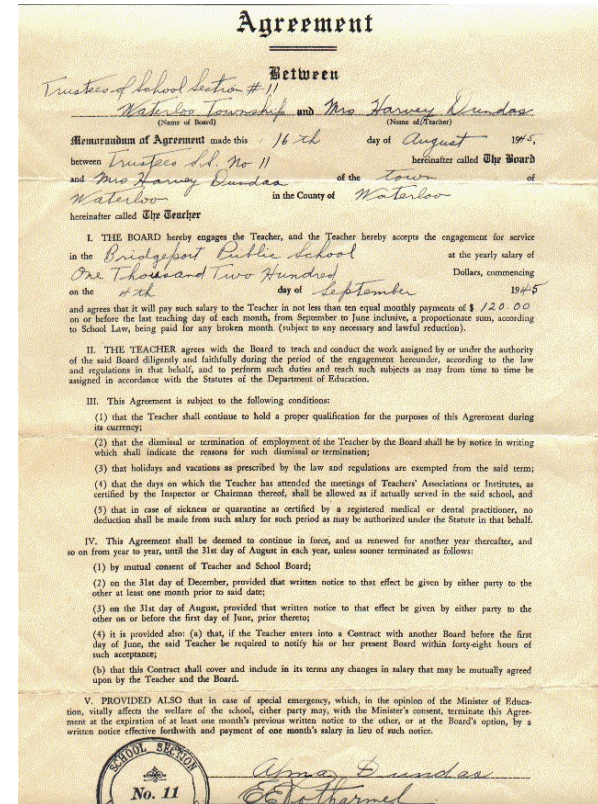
- Contract RP must be-
  - ✓ Suitably competent i.e. qualified, experienced, knowledgeable
  - ✓ Trained on GDP, SOPs, activities performed
  - ✓ Available to perform duties



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# Responsible Person Support

- Documentation-
  - ✓ Technical agreement between company and RP covering responsibilities and availability
  - ✓ Role profile for RP (& Deputy RP if applicable)
  - ✓ Variation to authorisation – Approved by the IMB



# Pest Control

- Ensure competence of provider
- Service level agreement between parties
- Bait map (approved by company)
- Records of pest control visits & company review
- Documentation of addressing recommendations from provider
- Include pest control in self inspections
- SOP on pest control



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# Security



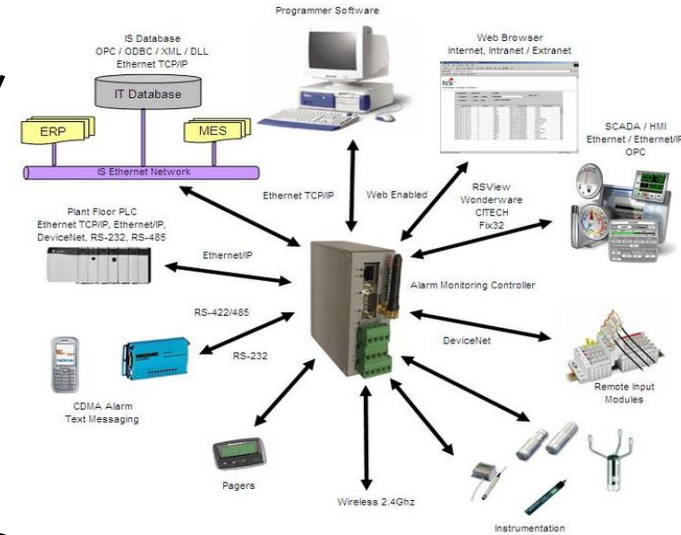
- Service Level Agreement between parties
- Training of security personnel on relevant items
- Security SOP – keys, CCTV, alarm codes, access
- NB – Controlled drugs on-site?



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# Alarm Monitoring

- Facility / Refrigerated storage / CD Safe / WH temperature / Essential equipment
- Documented in an SOP
  - Response times
  - Receivers of alarm notifications
  - Responsibilities
  - Escalation of issue
- Service level agreement with provider



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# Waste Management

- Wholesaler must ensure product does not re-enter supply chain
- Inventory maintained of waste
- SOP on waste management
- Storage of waste
- SLA with waste contractor
- Certificates of destruction
- Controlled Drug requirements
- NB – Other legislative requirements



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# Summary

- The Authorisation Holder maintains responsibility for contracted services
- Service Level Agreements in place
- Regularly review performance versus requirements



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# *Thank you*

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