



Responsible Person Medicinal Products

The Human Medicines Regulations require a distributor to designate a Responsible Person(s), named on the applicable licence. Regulation 45 and the EU GDP Guide set out the requirements and the responsibilities. Where the RP is contracted to a company, the duties remain the same as for those of the permanently employed RP.

Technical

the individual can...

Perform duties including:

Quality Management-the individual shall ensure that a quality management system proportionate to the distributor's activities is implemented and maintained including:

- quality risk management
 - corrective and preventative actions (CAPA) to address deviations
 - change control
 - measurement of performance indicators and management review
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Personnel-the responsible person is required to:

- understand their own responsibilities
 - carry out all duties in such a way as to ensure that the wholesale distributor can demonstrate GDP compliance
 - define personal and staff roles, responsibilities and accountabilities and record all delegated duties
 - ensure that initial and continuous training programmes are implemented and maintained
 - ensure all personnel are trained in GDP, their own duties, product identification, the risks of falsified medicines and specific training for products requiring more stringent handling
 - maintain training records for self and others and ensure training is periodically assessed
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Premises & Equipment

- ensure that appropriate standards of GDP are maintained for own premises and contracted storage premises
 - identify medicinal products, legal categories, storage conditions and different Marketing Authorisation types
 - maintain the safety and security of medicinal products within the appropriate environments, including product integrity and product storage
 - use the appropriate systems to segregate, store and distribute medicinal products
 - maintain records for the repair, maintenance, calibration and validation of equipment including computerised systems
 - ensure storage areas are temperature mapped, qualified and validated
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Documentation-the individual shall focus on:

- the accuracy and quality of records
- contemporaneous records
- records storage
- maintaining comprehensive written procedures that are understood and followed

- ensure procedures are valid and version controlled
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Operations

- carry out due diligence checks and ensure that suppliers and customers are qualified
 - ensure all necessary checks are carried out and that medicinal products are authorised for sale
 - manage authorised activities to ensure operations do not compromise the quality of medicines and can demonstrate compliance with GDP
 - demonstrate the application of activities and provisions in accordance with the wholesale distribution authorisation and of company processes and procedures
 - ensure that any additional requirements imposed on certain products by national law are adhered to e.g. specials, unlicensed imports & controlled drugs
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Complaints, returns, suspected falsified medicinal products and medicinal product recalls

- ensure relevant customer complaints are dealt with effectively, informing the manufacturer and/or marketing authorisation holder of any product quality/product defect issues
 - decide on the final disposition of returned, rejected, recalled or falsified products
 - approve any returns to saleable stock
 - coordinate and promptly perform any recall operations for medicinal products
 - co-operate with marketing authorisation holders and national competent authorities in the event of recalls
 - have an awareness of the issues surrounding falsified medicines
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Outsourced Activities

- approve any subcontracted activities which may impact on GDP
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Self-Inspection

- ensure that self-inspections are performed at appropriate regular intervals following a prearranged programme and necessary corrective measures are put in place
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Transportation

- apply the appropriate transport requirements and methods for cold chain, ambient and hazardous product
 - ensure all transport equipment is appropriately qualified
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Brokers

- ensure that transactions are only made with brokers who are registered
 - ensure that any broker activities performed are registered
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the individual has...

the prior relevant knowledge and experience related to the distribution of medicinal products

access to pharmaceutical knowledge and advice when it is required

knowledge of the products traded under the licence

if not a pharmacist or QP, one year's relevant practical and managerial experience of medicinal products

Compliance

the individual understands...

the role of MHRA in the licensing of medicines and as the competent authority including the risk-

based inspection process, the role of the enforcement group, the inspection action group (IAG), and resulting actions that can be taken due to non-compliance

the UK regulations in relation to wholesale distribution

the european pharmaceutical directive related to wholesale distribution of medicinal products

good distribution practice (GDP)

the importance of a clear reporting line to the wholesale distribution authorisation holder, senior manager and/or CEO

the individual shall...

employ due diligence in the discharge of their duties, maintaining full compliance to procedures and appropriate regulations

report to senior management, the marketing authorisation holder and the MHRA any suspicious events of which they become aware

additionally the individual understands...

the role of the professional bodies and organisations that regulate those supplying medicinal products to the public e.g. GPhC

the role of the home office in relation to the handling of controlled drugs

the role of the veterinary medicines directorate (VMD) in relation to veterinary medicines

the role of the european medicines agency (EMA) and use of EUDRAGMDP

the falsified medicines directive

the principles and guidelines of good manufacturing practice and how the principles of GDP maintain product quality throughout the distribution chain

Business Improvement

the individual can...

practise continuous improvement practices and utilise appropriate tools and techniques to solve problems

Functional & Behavioural

the individual has...

basic skills in

- English (level 2)
 - Mathematics (level 2)
 - ICT
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the individual can...

Autonomy

take responsibility for planning and developing courses of action, including responsibility for the work of others

exercise autonomy and judgement within broad but generally well-defined parameters

Management & Leadership

develop and implement operational plans for their area of responsibility

manage diversity & discrimination issues

provide leadership for their team

Working with Others

ensure effective delegation whilst retaining ownership of the outcome

develop and maintain productive working relationships with colleagues and stakeholders
monitor the progress and quality of work within their area of responsibility

Personal Development

manage their professional development by setting targets and planning how they will be met
review progress towards targets and establish evidence of achievements

Communication

put across ideas in clear and concise manner and present a well-structured case
communicate complex information to others

Business

understands the business environment in which the company operates
has an appreciation of the industry sector and competitors

Customers

understands the customer base and is aware of customer requirements

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