Managerial aspects

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Aspects of Compounding

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Disclosure Statement

Conflict of interest :

nothing to disclose

Managerial aspects

- Introduction
- Qualification of personnel
- Outsourcing
- Discussion and questions

Introduction

Pharmacy in University Hospital Maastricht:

- 8 qualified hospital pharmacists
- 1 QA pharmacist
- 5 trainees / project pharmacists
- 50 pharmacy technicians

- Since September 15, 2010 : GMP-z

University Hospital in Maastricht

Preparations for individual patients
Clean rooms TPN and cytostatic agents

Qualification of personnel

- Required in the GMP (-z), chapter 2
- It includes everyone (technicians, pharmacists, technical personnel)

Personnel in GMP

'There must be sufficient qualified personnel to carry out all the tasks which are the responsibility of the organisation.

Individual responsibilities should be clearly understood by the individuals and recorded. All personnel should be aware of the principles of GMP that affect them and receive initial and continuing training, including hygiene instructions, relevant to there needs'.

An approach of qualification

- Identity training requirements and make programme:
  - New employee (experience, background)
  - Annually (new tasks, sufficient experience)
- Execute training
- Use mentor or 'train the trainer' concept
- Document the training (if not documented: it is not done !)
- Sign off training / qualification by: employee, trainer and manager
- Keep records and make sure it remains up-to-date

Example of overview skills pharmacy technicians

Task / Pharmacy technician	Work in Laminar flow cabinet	Prepare Cytostatic drugs	Prepare TPN
A	Q	Q	-
B	Q	-	Q
C	Q	L	L
D	L	-	L
Z	Q	Q	Q

Q = qualified
L = learning
- = can not perform this task

Example of qualification work in aseptic area

PROD: Aseptisch werken in de LAF-kast

Soort document	Werkinstructie		
Status document	Geldig		
Datum document	26-04-2010	Geldig tot:	26-04-2012
Code document	P-WI-081211-03		
Documentbeheerder	Documentbeheerder Productie		
Auteur	Quint D., apothekersassistente		
Co-auteur			
Beoordelaar -1-	Plas van de A., ziekenhuisapotheker KFO		
Beoordelaar -2-	Smits C., apothekersassistente		

Autorisatie

Veldhorst N., ziekenhuisapotheker

Example of qualification work in aseptic area

B	**BEREIDING**		
16	Brengt VTGM-dossier de goederen sluis.	2e (Z)-APO
17	Omkleden en hygiëne: *X-WI-100309-01: PROD: Kledingprocedure*	AA Cytostatica en Omloop
18	Vult logboeken in, of checkt of de logboeken ingevuld zijn voordat met de VTGM-handelingen wordt gestart.	AA Cytostatica / omloop
19	Plakt de geparafeerd(e) etiket(ten) op VTGM-voorschrift(en).	Omloop
20a	Controleert of het cytostaticum al voor toediening gereed mag worden gemaakt, of dat gewacht moet worden op een signaal van de afdeling.	
20b	Zet de benodigdheden klaar per bereiding *P-WI-100630-01 PROD: werkwijze VTGM cytostatica*	AA Cytostatica aanschrijven
21	Controleert de klaargezette flacon(s) cytostaticum en/of immunomodulantium en benodigdheden a.h.v. VTGM-voorschrift.	AA Cytostatica
22	Aseptische VTGM-handelingen worden uitgevoerd volgens protocol *P-WI-081211-03: PROD: aseptisch werken in de LAF-kast*	AA Cytostatica en Omloop
23	Parafeert het etiket op het VTGM-voorschrift voor controle	Omloop

Example of qualification: work in aseptic area (laminar flow cabinet)

PERSONEEL: Kwalificatie apothekersassistent VTGM

Checklist: Inwerkschema VTGM medewerker

Deelgebied: Productie

Naam: Anna de Vries

	Taak	AA	Mentor	Datum
21	Controleert de klaargezette flacon(s) cytostaticum en/of immunomodulantium en benodigdheden a.h.v. VTGM-voorschrift.			
22	Aseptische VTGM-handelingen worden uitgevoerd volgens protocol : *P-WI-081211-03: PROD: aseptisch werken in de LAF-kast*			
23	Parafeert het etiket op het VTGM-voorschrift voor controle			

Training record: an example

PERSONNEL: Qualification Pharmacy Technician

Name: Anna de Vries

Education:

- High school
- Undergraduate
- Pharmacy technician

Skills
Qualified for: • work in laminar flow cabinet • prepare TPN
Learning: • prepare cytostatic drugs
Enclosures: • Checklist Qualification laminar flow cabinet • Checklist Prepare TPN

Why and how to document qualification for pharmacists?

- General answer: 'we know enough since we follow 3-4 years of training hospital pharmacy
- This is a general training
- Document the specific training for the area for which you are responsible, or replace a colleague
  - Courses
  - Intructions, SOP's, workinstructions
  - Training by predecessor or colleague
- Signed statement Head of Department

Qualification of pharmacists

(tasks, responsibilities, accountability matrix)

Task / Pharmacist	Clinical support	Production	QA	Laboratory	Medical gasses
A	X				
B		X			
C			B		X
D	B			X	
Z			X		

X = responsible and accountable

B = back up, can execute the tasks

Example of qualification pharmacist

Apotheker Kwaliteitszorg

De heer Dr. W.B.J. Mens, apotheker, is door zijn kennis en ruime ervaring met o.m. wet- en regelgeving in de farmaceutische industrie in diverse posities waaronder Registratie-afdeling en Productie geschikt om zijn functie als apotheker Kwaliteitszorg binnen de ziekenhuisapotheek van het azM uit te oefenen.

Maastricht, 29-07 **2010**

Drs. E. Frankfort, waarnemend hoofd Klinische Farmacie en Toxicologie

E Frankfort

Example of qualification pharmacist

azM | **PERSONEEL: D en O: Kwalificatie waarnemen ziekenhuisapotheker D en O**

Checklist: inwerkschema ziekenhuisapotheker
Deelgebied: **D&O**

Ziekenhuisapotheker kent:		**Datum**	**Paraaf**	
			Mentor	**(Z)-APO**
1	Globaal het logistieke proces in het ziekenhuis (Ontvangst en afleveren goederen magazijn, R-medicatie, Uitgifte, Bestellen/inkoop geneesmiddelen) *D-WI-281009-08 LOGISTIEK: Ontvangst en opslag geneesmiddelen* *D-WI-090505-03 LOGISTIEK Leveringen vanuit Centraal Apotheek Magazijn* *D-WI-090505-01 LOGISTIEK: Medicatie op naam (R-medicatie)* *X-PR-071022-01 LOGISTIEK Quarantaineregeling* *D-WI-281008-03 LOGISTIEK Bestellen van geneesmiddelen*	8-6-10		
2	De werkwijze van het controleren en deblokkeren van geneesmiddelkaarten in Pharma. Aandachtspunten: • Aantal basiseenheden = code • Tabblad Groepering • Tabblad Medicatie • Tabblad Doseerschema • Geneesmiddelen niet G-standaard *D-WI-100107-02 PHARMA: Aanmaak en onderhoud van artikelkaarten*	8-6-10		
3	De werkwijze van het vervangen van geneesmiddelkaarten in Pharma • Controle vervangend geneesmiddel • Controle medicatieopdrachten • Doorgegeven aan zapo KFO ivm medicatieprotocollen *D-WI-091217-01 LOGISTIEK: Vervangen artikelkaart in Pharma*	8-6-10		
3	De werkwijze van het retour nemen van (koelkast) geneesmiddelen.			

Summary qualifications personnel

- GMP: person can only perform task when trained
- Responsibility of management
- Qualification is only valid if it is signed
- Make sure you keep it up to date
- Trainer should be qualified (document this)
- General overview is useful managerial tool

Managerial aspects

- Introduction
- Qualification of personnel
- ➢ **Outsourcing**
- Discussion and questions

Outsourcing

Reasons for outsourcing; some examples:

- Strategic decision:
  - Focus on specific activities
  - Required investments can not be made
  - Specific knowledge is lacking
- Shortage (qualified) personnel
- Temporary decision

GMP on Outsourcing

'Contract manufacture and analysis must be correctly defined, agreed and controlled in order to avoid misunderstandings which could result in a product or work of unsatisfactory quality. There must be a written contract between the Contract Giver and the Contract Acceptor which establishes the duties of each party. The contract must clearly state the way in which the Qualified Person releasing each batch of product for sale exercises his full responsibility'.

Assume you contract activities for TPN to another organisation ..

What is required for this outsourcing?

- ..
- …
- ….

What is required for Outsourcing?

- Contract, general terms
- Quality contract
- Make sure your contractor has appropriate licence to operate
- Audit or equivalent

Contract General terms

Scope

- List of products
- Prices
- Customer Services
- Responsibilities contract giver and contract acceptor
- Should be signed by responsible (managing) directors
- Liabilities (if applicable)
- Duration

Note: not all inclusive

Quality Contract / Agreement

Should include:

Define:

- Quality of product (such as specifications, stability, in process controls)
- Batch documentation and/or Certificate of Analysis
- GMP licence
- Deviations
- Complaints
- Recalls
- Include right of audit
- Signed by QA and head of Hospital Pharmacy

When are contracts required?

- ....
- ……..

When are contracts required?

- Outsourcing productions, analytical activities
- Third parties (also in case of service within hospital):
  - Microbiological testing
  - Sterility testing
  - Cleaning
  - Technical services
  - IT (example software)
  - Production equipment

Is a contract useful or useless ?

- It is a lot of work: waste of time
- We shall trust each other

- GMP requires it
- Decision is up to your organization
- Advantage:
  - Clear understanding what is required
  - Responsibilities defined
  - Avoids conflicts

Discussion and Questions