‘Why be average when you can be excellent’

- Implementing a Training and Assessment Programme to meet the Medicines and Healthcare products Regulatory Agency (MHRA) Training Standards

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INTRODUCTION

The Pharmacy Production unit at Gloucestershire Royal Hospital is inspected by the hospitals inspection authority, the Medicines and Healthcare products Regulatory Agency (MHRA).

MHRA:
“The MHRA protect and improve the health of millions of people every day through the effective regulation of medicines and medical devices, underpinned by science and research”

Within our department there was no formal training programme to determine that staff were competent with their daily duties to meet with the current standards of the Medicines and Healthcare products Regulatory Agency.

TRAINING:
“Organised activity aimed at imparting information and/ or instructions to improve the recipient’s performance or to help them attain a required level of knowledge or skill”

TRAINING PROGRAMME:
“Significant long-term training activity which comprises of a series of sections and usually has a flexible time scale”

AIMS AND OBJECTIVES

The aim was to create a structured in depth training programme demonstrated by the use of an individual training file which is reviewed after a year with an outcome that all grades of staff can be trained efficiently, assessed and re-assessed as competent in their duties, ensuring everyone worked to the same standard, therefore improving patient safety.
This would be a very long process and would take a considerable amount of time to create, review and publish for the department.

METHODS

The Senior Pharmacist of the Pharmacy Production unit set aside 2 to 3weeks where the manufacturing management technicians would spend this time brainstorming, planning, and creating what will be a fully operational training programme.

BRAINSTORMING:
“Produce an idea or way of solving a problem by holding a spontaneous group discussion: "a brainstorming session”

It was decided after the brainstorming and planning session that a number of specific documents were needed to make a training programme work. Each document would be unique to its task and each one would contribute the full training of an individual for their duties.

Documents were created to clearly show the audit & assessment process for each member of staff. They included the following:

Standard Operating Procedures reading log.

- This document explains to the trainee the procedures that are required to be read. They must read these procedures, and sign to each corresponding number to show the assessor that they have read it.

Standard Operating Procedures 1st induction questionnaire.

- This is a 5 page document with 43 questions which relate to all the procedures the trainee must read. This will be marked by the manufacturing management technicians.

Reading File, including information on Good Manufacturing Practice (GMP).

- We recognised in our planning session that GMP plays a major part in responsibility for any member of staff whilst in the production unit, so we created a separate file that consists of reading material that the trainee must read for background knowledge. This would include detailed information on **GMP**, **Good Aseptic Practice** and **a basic introduction to clean rooms**. Alongside the reading file, we produced a questionnaire for each of the listed topics so we can ensure the trainee had a full understanding of these important subjects.

GMP:
“Good Manufacturing Practices (GMP, also referred to as 'cGMP' or 'current Good Manufacturing Practice') is the aspect of quality assurance that ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification”

Training document: a document was created for 25 processes.

- The training document, also known as the training method was split into a 3 stage process:

- **Stage 1** is basic information and details for the trainee about their upcoming training process.
- **Stage 2** includes the trainee observing the trainer undertake the process, followed by the trainee then carrying out the process themselves whilst under strict observation.
- **Stage 3** includes the trainee being signed off the training stage and passed on to the next stage where the Assessors will undertake the competency assessment.

Aseptic manufacturing technique assessments.

- This included:

- ensuring their dress code was acceptable as per policy.
- correct changing technique.
- use of a transfer hatch for ingredients / products.
- ensuring they carried out the correct procedures within the work zones.
- ensuring that their manufacturing technique is acceptable according to GMP standards.

We felt it was necessary to not just ensure the trainee can carry out the process correctly but we needed to ensure that they could carry out the manufacture of a product aseptically and to a very high standard.

Competency assessments on each process

- Three separate assessments would be carried out by the Assessors with the trainee on the process once the training is completed. Three passes are required.

Yearly re-assessments

- One assessment would be carried out by the Assessors once a year on each member of staff so we can ensure that the staff member can still carry out their duties competently and responsibly.

Chemotherapy training / assessments

- As chemotherapy is such a big part of the unit’s workload we felt it necessary for us to have a separate training document. This would include observations and assessments.

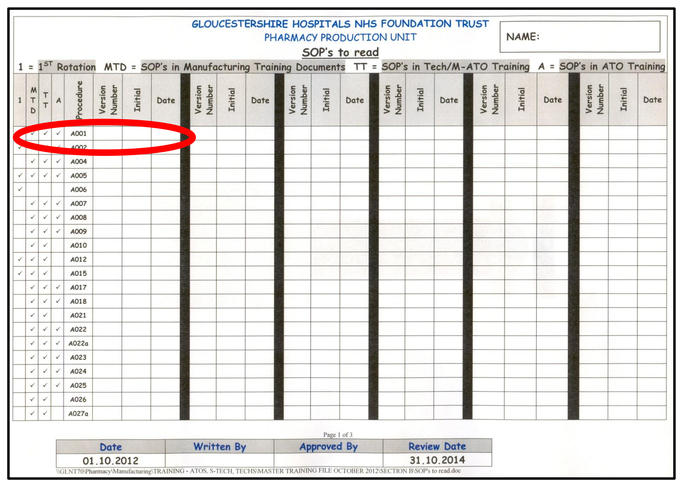
Quality control training / assessments

- Training and assessment would be carried out on the trainee ensuring that end of session finger dabs, swabbing and monitoring can be achieved competently.

THE DOCUMENTS – from a Pharmacy student’s perspective.

Lola
(1st Year Student)

“This is my 1st rotation into the Production unit, so the 1st thing I must do is read the procedures listed on this document. Once I have read A001, I will write the version number of A001 and then I will sign and date in the relevant box.
I will need to do this for every procedure, so it is a lot of work”



GLOUCESTERSHIRE HOSPITALS NHS FOUNDATION TRUST
PHARMACY PRODUCTION UNIT
NAME:
SOP's to read
1 = 1ST Rotation MTD = SOP's in Manufacturing Training Documents TT = SOP's in Tech/M-ATO Training A = SOP's in ATO Training

I	MTD	TT	A	Procedure	Version Number	Initial	Date	Version Number	Initial	Date	Version Number	Initial	Date	Version Number	Initial	Date	Version Number	Initial	Date	Version Number	Initial	Date
✓	✓	✓	✓	A001																		
✓	✓	✓	✓	A002																		
✓	✓	✓	✓	A004																		
✓	✓	✓	✓	A005																		
✓				A006																		
	✓	✓	✓	A007																		
	✓	✓	✓	A008																		
	✓	✓	✓	A009																		
	✓	✓		A010																		
✓	✓	✓		A012																		
✓	✓	✓		A015																		
	✓	✓	✓	A017																		
	✓	✓	✓	A018																		
	✓	✓		A021																		
	✓	✓	✓	A022																		
	✓	✓	✓	A022a																		
	✓	✓	✓	A023																		
	✓	✓	✓	A024																		
	✓	✓	✓	A025																		
	✓	✓	✓	A026																		
	✓	✓	✓	A027a																		

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Date	Written By	Approved By	Review Date
01.10.2012			31.10.2014

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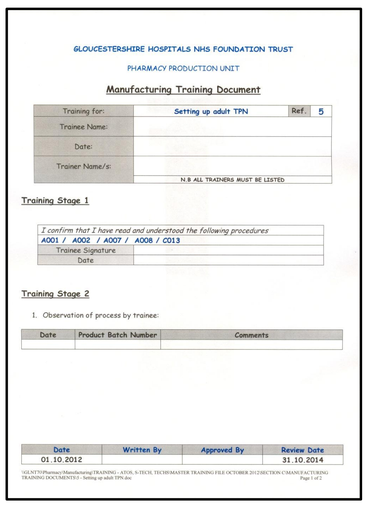

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PHARMACY PRODUCTION UNIT
Manufacturing Training Document

Training for:	Setting up adult TPN Ref. 5
Trainee Name:	
Date:	
Trainer Name/s:	
	N.B ALL TRAINERS MUST BE LISTED

Training Stage 1

I confirm that I have read and understood the following procedures
A001 / A002 / A007 / A008 / C013
Trainee Signature
Date

Training Stage 2

1. Observation of process by trainee:

Date	Product Batch Number	Comments

Date	Written By	Approved By	Review Date
01.10.2012			31.10.2014

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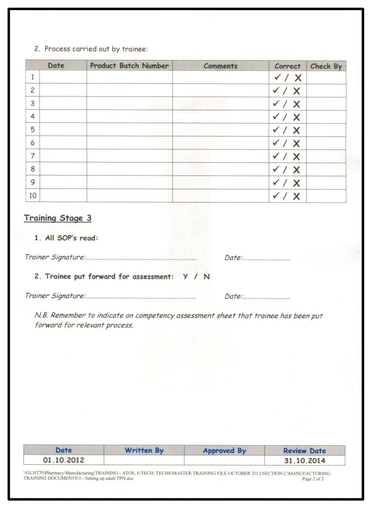

2. Process carried out by trainee:

	Date	Product Batch Number	Comments	Correct	Check By
1				✓ / X	
2				✓ / X	
3				✓ / X	
4				✓ / X	
5				✓ / X	
6				✓ / X	
7				✓ / X	
8				✓ / X	
9				✓ / X	
10				✓ / X	

Training Stage 3

1. All SOP's read:

Trainer Signature:..... Date:.....

2. Trainee put forward for assessment: Y / N

Trainer Signature:..... Date:.....

N.B. Remember to indicate on competency assessment sheet that trainee has been put forward for relevant process.

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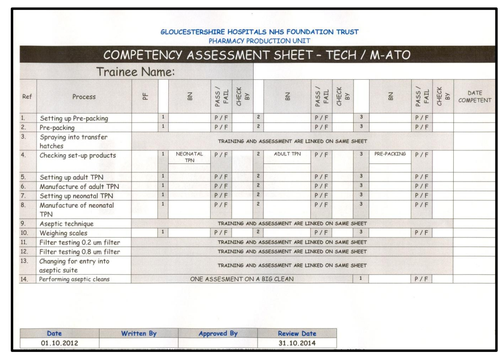
\GLNT70\Pharmacy\Manufacturing\TRAINING - ATOS, S-TECH, TECHS\MASTER TRAINING FILE OCTOBER 2012\SECTION C\MANUFACTURING TRAINING DOCUMENTS\5 - Setting up adult TPN.doc Page 2 of 2

“I am due to start my training on ‘setting up of adult PN (parenteral nutrition).
I need to ensure I have filled out page 1 correctly, and signed to say I read the procedures that corresponds with this process. I then observe someone who is already trained in setting up an adult bag. I then undertake the task myself until I and the trainer feels competent enough to forward me on for assessment”

“So now I am competent in setting up adult PN, I can now have my 3 separate assessments. My manufacturing Assessors will observe and assess me setting the adult PN up by myself. I must pass all 3 assessments to be able to set up adult PN in the future on my own”



GLOUCESTERSHIRE HOSPITALS NHS FOUNDATION TRUST
PHARMACY PRODUCTION UNIT
COMPETENCY ASSESSMENT SHEET - TECH / M-ATO
Trainee Name:

Ref	Process	PF	IN	PASS / FAIL	CHECK BY	IN	PASS / FAIL	CHECK BY	IN	PASS / FAIL	CHECK BY	DATE COMPETENT
1.	Setting up Pre-packing		1	P / F	2		P / F	3		P / F		
2.	Pre-packing		1	P / F	2		P / F	3		P / F		
3.	Spraying into transfer hatches	TRAINING AND ASSESSMENT ARE LINKED ON SAME SHEET										
4.	Checking set-up products		1 NEONATAL TPN	P / F	2	ADULT TPN	P / F	3	PRE-PACKING	P / F		
5.	Setting up adult TPN		1	P / F	2		P / F	3		P / F		
6.	Manufacture of adult TPN		1	P / F	2		P / F	3		P / F		
7.	Setting up neonatal TPN		1	P / F	2		P / F	3		P / F		
8.	Manufacture of neonatal TPN		1	P / F	2		P / F	3		P / F		
9.	Aseptic technique	TRAINING AND ASSESSMENT ARE LINKED ON SAME SHEET										
10.	Weighing scales		1	P / F	2		P / F	3		P / F		
11.	Filter testing 0.2 um filter	TRAINING AND ASSESSMENT ARE LINKED ON SAME SHEET										
12.	Filter testing 0.8 um filter	TRAINING AND ASSESSMENT ARE LINKED ON SAME SHEET										
13.	Changing for entry into aseptic suite	TRAINING AND ASSESSMENT ARE LINKED ON SAME SHEET										
14.	Performing aseptic cleans	ONE ASSESMENT ON A BIG CLEAN				1		P / F				

Date	Written By	Approved By	Review Date
01.10.2012			31.10.2014

RESULTS

The Production Unit now has a fully functioning, concise and well structured training programme. The training programme consists of approximately 50 separate documents all relating to an individual topic or process. These will include the tasks already listed in the method section, as well as the individual training methods / documents covering each of the processes we feel necessary to be trained in, which equals a total of 29 processes (29 documents)
Included in the 50 documents are brief sub-sections that sets out the training criteria and the responsibilities of each member of staff relating to their training. We also have other sub-sections that are allocated to filing the staff members validation paperwork, certificates and any other evidence they may have collected.
This means that each member of staff has sufficient and continuous evidence of their training and competency assessments which will be stored in their own individual training file. Their training files will stay with them for as long as they working within the production unit.

The Production Unit now has the MHRA approval for our training programme.

The Production Unit had an “outstanding” review in 2012 from Tim Sizer, our Regional Quality Control Inspector. In 2013 we received a statement from Tim regarding our training programme:

“Training programmes for staff involved in aseptic work are vitally important and as an auditor this is something I take great interest in. At Gloucester the programme is varied to suit the specialist requirements of each group of staff and includes reading, quizzes, validation records and logs (plus revalidation and refresher training). This is a very good process with appropriate levels of detail and is followed up with an annual reassessment. I found the Gloucester programme and staff records to be an impressive example of it's type, and recommend others to follow suit”.

Tim Sizer

CONCLUSION

The staff in our department now all work to the same standards. They are now trained and assessed as competent and confident and this is regularly monitored. This allows us to continuously improve and monitor the Trust’s top priority, **patient safety**.

REFERENCES

http://www.mhra.gov.uk/#page=DynamicListMedicines
http://www.google.co.uk
http://en.wikipedia.org/wiki/