PHARMACY GCP COMPLANCE CHECKLIST

This checklist aims to provide R&D Departments and Pharmacy Clinical Trial Teams with a simple tool to asses the GCP compliance of the clinical trial/IMP management services provided by NHS Pharmacy Departments and focuses on the policies, procedures and operational aspects of these services with particular attention paid to compliance with the requirements of the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended) and the Department of Health Research Governance Framework for Health and Social Care (2005).

The checklist should take no more than 30 minutes to complete

PHARMACY POLICIES, PROCEDURES, FACILITIES AND RESOURCES

#	Details	Yes	No	N/A	Don't know	Comments
	Pharmacy Staff & Training					
1	**Do Pharmacy have a policy document covering the safe handling of medicines used in clinical trials, including a statement listing the responsibilities the clinical trial investigator will delegate to the pharmacy department?** (a(as per Section 2.2 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					
2	**Is there a designated member of staff appointed who has overall responsibility for the pharmacy clinical trial service?** (as per Section 2.2 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					**Pharmaceutical Coordinator/Designated Clinical Trials Pharmacist** It is recommended that a member of the pharmacy staff should have an assigned role as pharmaceutical coordinator in relation to each clinical trial involving a medicine in a hospital. In most cases this would be a designated clinical trials pharmacist. This coordinator would be the contact person for any local or chief investigators, pharmaceutical companies or others involved in the arrangements for supplies for the trial, including to ensure that the formulation, presentation, and storage of clinical trial medication

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						are appropriate. (DoH/MRC – Management Issues for Clinical Trials, 2004 – Accessed from: http://www.ct-toolkit.ac.uk/_db/_documents/Hospitals.pdf)
3	**Are clinical trial services provided by designated pharmacy staff?** (as per Section 2.2 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					
4	**Are all pharmacy staff that provide clinical trial services adequately qualified, trained and experienced?** **Have they all received GCP training every 2 years?** (as per Section 2.2 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839) (as per Part 2.2 of Schedule 1 of the Medicines for Human Use (Clinical Trials) Regulations 2004 as amended – Accessed from: http://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf http://www.legislation.gov.uk/uksi/2006/1928/pdfs/uksi_20061928_en.pdf)					**Good Clinical Practice (GCP) Training** For the purposes of maintaining Good Clinical Practice, all pharmacy, nursing and other staff involved in a clinical trial should be trained for undertaking their role in that trial. A record should be kept of such training. All pharmacy staff will need to receive training appropriate to their roles in clinical trials. All training should be documented, and be available for inspection. (DoH/MRC – Management Issues for Clinical Trials, 2004 – Accessed from: http://www.ct-toolkit.ac.uk/_db/_documents/Hospitals.pdf)

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5	**Have all designated pharmacy staff that provide clinical trial services received training on the specific trial protocol?** (as per Section 2.2 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839) (as per Part 2.2 of Schedule 1 of the Medicines for Human Use (Clinical Trials) Regulations 2004 as amended – Accessed from: http://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf http://www.legislation.gov.uk/uksi/2006/1928/pdfs/uksi_20061928_en.pdf)					**Do staff preparing the product need to be trained in the protocol?** Yes, Part 2, 2 of SI 2004/1031 (as amended) requires that each individual involved in conducting a trial shall be qualified by education, training and experience to perform his tasks. Staff preparing product therefore need to be trained in the trial-specific requirements of the protocol applicable to the preparation of product, to ensure adherence to the trial protocol and preserve the credibility and integrity of the data. (MHRA Guidance – Accessed from: http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodClinicalPractice/Frequentlyaskedquestions/index.htm#IM13) **Do staff administering the product need to be trained in the protocol?** Yes, and there must be documented evidence of this training. It is important that the person administering the product has knowledge of the protocol which the subject receiving that product is participating in. There will be some aspects within protocols that are not particularly relevant for those administering the product but it is expected that the staff member administering the product has appropriate knowledge of the study (MHRA Guidance – Accessed from: http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodClinicalPractice/Frequentlyaskedquestions/index.htm#IM13)

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						Extra precautions need to be taken with these products to ensure safety and security in their use There are a variety of types of trial, some of which are comparisons of existing marketed products used within their licensed indications. However, as many products under investigation may be unfamiliar to the staff handling them and/or may be coded to prevent ready identification by either the investigator or the patient, extra precautions need to be taken with these products to ensure safety and security in their use. (As per Section 8.2 of The Safe and Secure Handling of Medicines (2005) – Accessed from: http://www.rpharms.com/support-pdfs/safsechandmeds.pdf)
6	**Have all pharmacy staff that provide clinical trial services received GCP training every 2 years?**					
7	**Do all pharmacy staff that provide clinical trial services have a 'CV & Training' file that includes the following?** • **Training records** • **CV** • **Job Descriptions**					**What records of training should be maintained?** The Clinical Trial Regulations (Schedule 1 Part 2 point 2) require in the conditions and principles that apply to all clinical trials that 'Each individual involved in conducting a trial shall be qualified by education, training and experience to perform his tasks'.

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	(as per Section 2.2 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					In order to demonstrate the training has occurred, documentation should be maintained and retained. The extent and content of this documentation is a business decision, but typically includes a current job description dated and signed by the post-holder and their management (to demonstrate the date on which current roles and responsibilities have been agreed), a curriculum vitae (to demonstrate current and previous, relevant education and experience, preferably signed and dated to confirm the date of the document and ownership by the named individual), confirmation GCP training has taken place (including clear reference to the framework used in the training), and role-specific training relevant to the post-holder's duties and clinical trial role(s) and responsibilities. Additionally for each trial an individual contributes to there should be documentary evidence that they have had relevant trial-specific and (where required) therapeutic area training. These records should be maintained as trial-supporting documents (either centrally or with the individual trial) for as long as they may be needed to support historical reconstruction of the trial. It is recommended that records are reviewed before an individual leaves an organisation to ensure the record retained in the archives

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						is complete and accurate. (MHRA Guidance - Accessed from: http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodClinicalPractice/Frequentlyaskedquestions/index.htm#T1)
8	**Do the pharmacy job descriptions provide clarity with regards to responsibility and accountability for clinical trials?** (as per Section 2.2 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					
9	**Does the pharmacy hold training records and signature logs for those staff involved in clinical trial activities?** (as per Section 2.3 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					The identities of all those involved with receipt, dispensing, issue, administration, and disposal of all medicines should be recorded (As per Section 8.2.4.1 of The Safe and Secure Handling of Medicines (2005) – Accessed from: http://www.rpharms.com/support-pdfs/safsechandmeds.pdf)
	Pharmacy Facilities					
10	**Are all IMPs stored and dispensed from the Pharmacy?**					**Do pharmacies always have to be involved in the receipt and storage of investigational medicinal product(IMPs)?** There is no legal requirement for pharmacy involvement. However, lack of pharmacy involvement has often been associated with

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						negative inspection findings in that often poor record keeping and accountability have been identified. The Institute of Clinical Research and the Royal Pharmaceutical Society of Great Britain has produced guidance on this topic, which states that, 'When a clinical trial is taking place in a hospital all IMPs should be stored and issued by the hospital pharmacy and managed to the same standards as licensed medicines. IMPs must not be stored in offices, clinics or ward areas unless by prior agreement with pharmacy'. (MHRA Guidance – Accessed from: http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodClinicalPractice/Frequentlyaskedquestions/index.htm#IM13) **All medicines, or constituent ingredients, for clinical trials should be ordered, stored and dispensed by the hospital pharmacy** As part of the NHS controls assurance arrangements in England, a set of standards have been published on Medicines Management (safe and secure handling) against which NHS bodies report. Criterion 9 is that "the supply of medicines for clinical trials is undertaken in accordance with relevant legislation and best practice guidelines", with guidance that "all medicines, or constituent ingredients, for clinical trials should be ordered, stored and

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						dispensed by the hospital pharmacy." (Medicines Management Standard (2003) – Accessed from: http://www.dhsspsni.gov.uk/medicines_03.pdf) **The Safe and Secure Handling of Medicines** The general route of purchasing, distribution and storage of clinical trial products should follow that of other medicines, except where there are special arrangements for supplies for commercial company trials of new medicines. Stocks of trial medicines should not be maintained on wards, clinics, university departments or in private offices unless the trial involves a medicine used in an emergency situation, when sufficient stocks should be held in the ward or department for immediate use. (As per Section 8.2 of The Safe and Secure Handling of Medicines (2005) – Accessed from: http://www.rpharms.com/support-pdfs/safsechandmeds.pdf) **Samples and clinical trial materials**

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						Samples and clinical trial materials should be received from the manufacturer or his representatives only by a pharmacist. They should not be accepted on the ward, but if found there they should be sent to the pharmacy department. Wards may participate in clinical trials with appropriate staff and training Properly-labelled clinical trial medicines brought in by a patient on admission, as part of current medication, can be checked by an authorised prescriber in the ward setting, noted, prescribed and administered as directed. (As per Section 9.7, 10.6, 11.7, and 12.7 of The Safe and Secure Handling of Medicines (2005) – Accessed from: http://www.rpharms.com/support-pdfs/safsechandmeds.pdf) **Clinical Trial IMPs to be Held in the Hospital Pharmacy** This note takes as a principle that all medicinal product clinical trial supplies in hospitals should be held in the hospital pharmacy unless there are specific reasons for particular supplies to be held on a ward, clinic or department – this may arise when, for example, the medicine has been dispensed as a supply for administration to an individual patients. There should be no ward or department stocks of such trial supplies unless urgent administration is a requirement

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						of the trial, where the arrangements for storage would need to be agreed with the pharmacy. (DoH/MRC - Management Issue for Clinical Trials, 2004 – Accessed from: http://www.ct-toolkit.ac.uk/_db/_documents/Hospitals.pdf) **IMP storage and handling** All medicines should be managed by the pharmacy including clinical trial materials. It is recommended that specially manufactured or assembled IMPs (after QP release) be kept in a separate and secure storage area with sufficient room to ensure that there is no confusion between trial and other supplies. In trusts with a large number of clinical trials, holding stocks of marketed products intended for a trial (where the use is in accordance with the marketing authorisation), separate from supplies for normal outpatient dispensing, can facilitate control and work flow in the pharmacy. (DoH/MRC - Management Issue for Clinical Trials, 2004 – Accessed from: http://www.ct-toolkit.ac.uk/_db/_documents/Hospitals.pdf)
11	**Does the Pharmacy have facilities to allow for IMPs to be stored separately from normal pharmacy stock in an area with**					**Common inspection findings:**

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	restricted access? (as per Section 3.1 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					• Inadequate provisions for storage of IMPs i.e. not kept separate to usual clinical supplies • http://www.ct-toolkit.ac.uk/_db/_documents/mhra_inspection_guide_311006.doc
12	**Are IMPs that are returned by patients or have expired stored separately from unused IMPs?** (as per Section 3.1of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					
13	**For clinical trials materials and IMPs - Are all fridges and freezers fitted with thermometers that record minimum and maximum temperatures and with an alarm system to alter staff if the temperature falls outside the specified range?** (as per Section 3.2 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					
14	**Does the Pharmacy have written procedures in place that specify the actions to take when the storage conditions fall outside the specified range?**					

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	(as per Section 3.2 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					
15	**Is regular temperature monitoring of IMP storage facilities undertaken and these records archived?** (as per Section 3.2 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					**What records should be maintained if the product is a refrigerated product or requires frozen storage?** Records should be maintained to demonstrate that the product was stored within the required temperature range during transit and has continued to be stored within the required temperature range prior to use. Records should be maintained of the checks made on the storage temperature including calibration records of temperature monitors used. It is expected that there is traceability in the calibration records to National Standards (for example a 'reference thermometer' may be annually certified traceable to National Standards). (MHRA Guidance – Accessed from: http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodClinicalPractice/Frequentlyaskedquestions/index.htm#IM13)
16	**Are suitable archiving facilities available for archiving of pharmacy trial files?** Does the system used for archiving allow for prompt retrieval of any pharmacy study file or of non-study specific documentations (such as pharmacy SOPs, original pharmacy temperature					

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	monitoring record and training records of pharmacy staff)? Note - Staff training records for an individual clinical trial must be archived with the pharmacy study file to ensure that these records are available for audit or regulatory inspection (as per Section 3.3 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					
	Pharmacy Resources					
17	**Does Pharmacy have adequate resources available to provide a pharmacy clinical trial service so that research does not inappropriately divert pharmacy NHS resources from the provision of patient care?** (as per Section 4.1 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					**Adequate & Appropriate Resources** Facilities devoted to clinical trials need to be appropriate to the volume of work involved. Equipment can be validated and checked as part of the normal NHS independent quality control audit at regular intervals. (DoH/MRC - Management Issue for Clinical Trials, 2004 – Accessed from: http://www.ct-toolkit.ac.uk/_db/_documents/Hospitals.pdf)
	Is there sufficient resource available to ensure that clinical trial services can be maintained during vacations and short-term sickness?					

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18	**Has a management system been established within the Trust whereby pharmacy is contacted in advance of the Trust agreeing and signing the model CTA?** (as per Section 4.4 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					When the pharmacy is not included within the trial agreement the pharmacy should set up a separate agreement with the sponsor. The Trust's R&D Department should be consulted and the process documented in an SOP (as per Section 4.4 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839) **Ensure that the pharmacy department is contacted in the early stages about proposals for a clinical trial** Good relations are to be fostered between the hospital trust's R&D managers and trust pharmacy management, and procedures put in place to ensure that the pharmacy department is contacted in the early stages about proposals for a clinical trial which would be regulated by the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031). It is recommended that resources should be made available so that the appropriate level of pharmaceutical support can be provided for all such trials as part of Good Clinical Practice processes (in addition to the costs of manufacturing or assembly of investigational medicinal products used in individual trials). **Protocols of proposed clinical trials should be made available to**

#	Details	Yes	No	N/A	Don't know	Comments
						the pharmacy department in advance of a request for a clinical trial authorisation or ethics committee opinion, so that practical details such as doses and method of administration, packaging, labelling and study documentation for pharmacy appropriate for each individual trial, can be confirmed. A copy of the up to date protocol of each approved clinical trial that involves a medicine, should be held for reference purposes by the pharmacy department that supplies the medicine. **Coordination with pharmacy staff** Information about a trial likely to be needed to be resolved with and understood by the pharmacy department includes: • Purpose of the trial • Explanation of the responsibilities of the various parties involved • Codes including for participant randomisation • Numbers and recruitment parameters of patients as trial participants • Description of the marketed product or specification of the IMP to be used, • and any relevant handling/COSHH data • Source of products to be used

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						• Labelling to be used • Name and contact details of the Chief Investigator, local investigators and • others involved in organising, managing or administering the trial (including the involvement of any university based a clinical trials unit providing overall coordination as part of a trial) • Documentation to be retained by the pharmacy. (DoH/MRC – Management Issues for Clinical Trials, 2004 – Accessed from: http://www.ct-toolkit.ac.uk/_db/_documents/Hospitals.pdf)
19	**Are all Pharmacy staff who are involved in the conduct of clinical trials (including dispensing activities) aware of the legislation and local requirements for:** • **the conduct of clinical trials (GCP)** • **the reporting of Adverse events and Serious Adverse Events** • **the reporting of suspected fraud, misconduct or other incidents?** (as per Section 6.2 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					

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20	**Are pharmacy staff involved in the Trust peer review process of clinical trial protocols?** (as per Section 7.2 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					**Protocols of proposed clinical trials should be made available to the pharmacy department in advance of a request for a clinical trial authorisation or ethics committee opinion**, so that practical details such as doses and method of administration, packaging, labelling and study documentation for pharmacy appropriate for each individual trial, can be confirmed. A copy of the up to date protocol of each approved clinical trial that involves a medicine, should be held for reference purposes by the pharmacy department that supplies the medicine. **Separation of responsibilities** There will ideally be a separation of responsibilities between: • the pharmacist advising the Ethics Committee • the clinical trials pharmacist (pharmaceutical coordinator) responsible for a trial, and (where there is a pharmacy manufacturing unit) 1. the production pharmacist responsible for the unit which manufactures the product 2. the qualified person responsible for the release of the locally manufactured product.

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						This will not always be practical in small units, but the principles of the separation of interest and responsibility is to be aimed for in all possible circumstances. (There may be exceptional circumstances in a small unit where it may not be possible to separate the role of the advisor to the Ethics Committee and the clinical trials pharmacist, but in such circumstances a *'Declaration of Interests'* in full, including all costings, should be made, to the chairman, before any discussions occur.) (DoH/MRC – Management Issues for Clinical Trials, 2004 – Accessed from: http://www.ct-toolkit.ac.uk/_db/_documents/Hospitals.pdf) Where there is a conflict of interest for the pharmacy department it must be declared (as per Section 7.2 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)
	Study Set-up					
21	**Do designated pharmacy staff review each protocol, assess the**					**Ensure that the pharmacy department is contacted in the early**

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	feasibility of the study, cost the work to be undertaken by the pharmacy department and where appropriate assess the impact for the Trust? (as per Section 9.1 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					**stages about proposals for a clinical trial** Procedures should be put in place to ensure that the pharmacy department is contacted in the early stages about proposals for a clinical trial which would be regulated by the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031). It is recommended that resources should be made available so that the appropriate level of pharmaceutical support can be provided for all such trials as part of Good Clinical Practice processes (in addition to the costs of manufacturing or assembly of investigational medicinal products used in individual trials). (DoH/MRC – Management Issues for Clinical Trials, 2004 – Accessed from: http://www.ct-toolkit.ac.uk/_db/_documents/Hospitals.pdf)
22	**Do Pharmacy clinical trials staff participate in the investigator meeting or the site selection visit and initiation meeting?** (as per Section 9.2 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					Pharmacy staff should use their professional expertise to review the protocol and explain the correct use and storage of any IMPs to other health professionals (e.g., investigators and research nurses) who may not be familiar with these (as per Section 9.2 of the Pharmacy Practice Guide, 2005)
23	**Are Pharmacy contacted by R&D as part of the clinical trial due diligence process to ensure that Pharmacy have the necessary facilities and licences in place to support the conduct of a**					**Manufacturing Requirements for IMPs** IMPs must be manufactured in a licensed production unit, authorized by the MHRA, in accordance with Good Manufacturing

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	proposed clinical trial? This is particularly important for trials where the Trust is acting as the sponsor of the Trial and where Pharmacy may need an MA(IMP) licence and/or be in a position to assess whether the exemption provided by Regulation 37 of SI 2004/1031 as amended is sufficient for the proposed activities.					Practice (GMP) and labeled in accordance with Annex 13, these IMPs must be released for use by a Qualified Person (QP). Note - The distinction between manufacturing, assembly and dispensing, and the circumstances where a QP is not required are defined in the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended). (as per Section 9.3 of the Pharmacy Practice Guide, 2005 and as per Regulations 36, 37 and 46 of SI 2004/1031 as amended) **When does the Regulation 37 (Exemption for hospitals and health centres) apply?** Regulation 36 requires IMPs to be manufactured, assembled or imported in accordance with a manufacturing authorisation (MIAIMP). Under the Regulation 37 exemption, hospitals and health centres are allowed to perform assembly activities for IMPs, without the need to hold a MIAIMP licence. Assembly is defined as: a. Enclosing the IMP in a container which is labelled, before the IMP is supplied or used in a clinical trial b. where the IMP is already contained in the container in which it is

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						to be supplied or used in a clinical trial, labelling the container, before it is supplied or used in a clinical trial, in that container. However, exemption is only applicable for hospitals or health centres performing the assembly and by hospitals or health centres actively involved as a clinical site for that trial (this exemption does not apply to commercial Phase I units). (MHRA Guidance – Accessed from: http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodClinicalPractice/Frequentlyaskedquestions/index.htm#IM10) **I work in a clinical trials unit situated in my local hospital. We have a MIA(IMP) and carry out assembly of IMPs for immediate use within the unit. However, the hospital production unit itself assembles IMPs and doesn't have a MIA(IMP). Is this permissible?** Section 37 of the clinical trials legislation contains a specific exemption which is relevant here. This exemption provides an exemption from the need for a hospital or health centre to hold a MIA(IMP) authorisation to assemble an IMP in a hospital or health centre, when the 'assembly' is carried out by a doctor or pharmacist, or under the supervision of a pharmacist. 'Assembly' is related to packaging and labelling, and not to the preparation of medicines

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						from their ingredients. The exemption applies only if the product is to be used exclusively in that hospital or health centre or any other that is a trial site for the clinical trial in which the product is to be used. This exemption does not apply to anyone else such as separate organisations which happen to be situated within a hospital or to companies which have a contract to supply hospitals or health centres. (MHRA Guidance – Accessed from: http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodManufacturingPractice/FAQ/IMP/index.htm#2)
24	**Does pharmacy request actual samples of the packaging and labeling of IMPs in advance of the commencement of recruitment of subjects to the clinical trial?** Purpose - Sufficient time should be allowed for a risk assessment of the product and for additional pharmacy labels to be produced if necessary prior to any dispensing (as per Section 9.4 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					**Labelling of IMPs** • In the UK, where a clinical trial involves a marketed medicine used within its marketing authorisation, the product can be labelled in accordance with the requirements for a dispensed medicine. The relevant aspects and make up of such labels are shown in section A below. • Guidance on the requirements of IMPs in other situations is given in Annex 13 of the EU's good manufacturing practices

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						documentation. (DoH/MRC – Labelling of IMPs, 2004 – Accessed from: http://www.ct-toolkit.ac.uk/_db/_documents/labelling.pdf) **When does Paragraph 26 (Annex 13 IMP Labelling Requirements) apply?** All IMPs for use within a clinical trial must be labelled in accordance with paragraph 26 of annex 13. This applies to not only the investigational product but also to any comparators and placebos used. In some cases, however, abridged labelling is permitted. Paragraph 26 lists the information which should appear on labels, but does allow some flexibility if the absence can be justified. This is often referred to as abridged labelling and is agreed on a trial-specific basis. The cases where this form of labelling is permitted are as follows: 1. For marketed product used within its marketing authorisation, the product can be labelled according to dispensed medicine requirements if this was approved as part of the CTA. However, sponsors may wish their

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						products be labelled following the guidance in Paragraph 32 of Annex 13 2. if the IMP being used is a drug product in a vial which needs to be reconstituted aseptically for the purposes of administration, then the vial would need Annex 13 labelling. (MHRA Guidance – accessed from: http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodClinicalPractice/Frequentlyaskedquestions/index.htm#IM10) **Note on Labelling operations** Adding patient specific labelling to a marketed product is part of dispensing in supplying to a patient. However it is an assembly operation where labels are prepared and attached in bulk in advance. There appear to be the following options associated with such labelling in advance: • Where a trial involves a series of separate dosage changes it would seem preferable to repack and label in an IMP manufacturing unit to provide for Good Clinical Practice. • Where a trial only uses a consistent dosage through out the trial, and there are large numbers of patients in the trial at

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						a single centre, it would be efficient to pre-assemble labelled supplies in the hospital (or health centre) making use of the exemption provisions of Regulation 37, leaving the individual patient details to be added as a dispensing operation. (DoH/MRC – Labelling of IMPs, 2004 – Accessed from: http://www.ct-toolkit.ac.uk/_db/_documents/labelling.pdf)
25	**Does Pharmacy check the packaging and labels of IMPs to ensure they comply with Good Manufacturing Practice (GMP) requirements and regulations and ensure that they are legible and understandable for the subject?** (as per Section 7.4 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					
26	**Where drug accountability forms, prescription forms and other associated forms are supplied by the sponsor, does the Pharmacy department review these with regard to the data they are designed to capture and their suitability for use within the pharmacy department? If so, how is this documented?** **Does the pharmacy department provide this documentation for non-commercial trials using IMPs?**					**Do records of accountability need to be maintained?** For those trials where the pharmacy provides the IMP on prescription from the investigator, there must be a full record of accountability maintained at the investigator site with summary evidence also held at the sponsor site. This means that all records of goods in, all records of goods dispensed and all records of goods returned or destroyed, including records for any marketed

#	Details	Yes	No	N/A	Don't know	Comments
	(as per Section 9.5 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					authorised products used as IMPs, comparators or adjuvant therapy must be kept. The records should be clear and it should be easy to rapidly determine the stock remaining at a site in case of an emergency such as an IMP recall. For pragmatic trials, where IMP is provided on prescription from a local or community pharmacy, the sponsor should develop a system to document batch numbers dispensed to each patient wherever this is possible. This is required to ensure that subject receives the correct medication and compliance with the treatment regimen which ultimately can affect data integrity. (MHRA Guidance – Accessed from: http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodClinicalPractice/Frequentlyaskedquestions/index.htm#IM13)
27	**Does the Pharmacy hold the code breaks for emergency unblinding?** (as per Section 9.8 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					In circumstances when the pharmacy does not hold the code break the pharmacy should ensure that there is a system in place for providing 24 hour cover to access the code-break for a clinical trial (as per Section 9.8 of the Pharmacy Practice Guide, 2005) **Is there any legislation which states how and where the code breaks for clinical trials should be stored?**

#	Details	Yes	No	N/A	Don't know	Comments
						The guidance from the Pharmaceutical Society states that 'The pharmacy should, where possible, hold the code breaks' The storage location of any code breaks is not specified in the legislation. What is of concern is the security of the blinding (ie that the blind cannot be broken without it being detected or code breaks removed/accessed by unauthorised personnel), ensuring that the ability to unblind is in place prior to or at the same time that IMP is made available to the investigator and that there is the ability to promptly unblind for a particular subject in an emergency. ICH GCP requires (section 5.13.4, 8.2.17) a documented procedure to be in place to describe how this is to be done. If the investigator only holds the envelopes (or IVRS access codes), what would happen should the investigator be unavailable? Is there an alternative way of breaking the blind? The pharmacy may have a role to play in the process, for example, would the pharmacy be contacted if the investigator/sponsor was unavailable? And is there a documented procedure for this to enable locum staff to follow this procedure? It is the robustness of the process that is important, how it is achieved is the responsibility of the sponsor/organisation. (MHRA Guidance – Accessed from: http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodC

#	Details	Yes	No	N/A	Don't know	Comments
						linicalPractice/Frequentlyaskedquestions/index.htm#IM13)
28	**Where the Trust acts as the Sponsor for a clinical trial, does the pharmacy provide 24/7 out of hours emergency cover for code break access (as per Articles 26 and 27 of Annex 13?)** **Is this procedures captured in an SOP and is it routinely tested to ensure that it works i.e., the number provided in called and 'dummy unblinding' exercises conducted?** (as per Section 9.8 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					In circumstances when the pharmacy does not hold the code break the pharmacy should ensure that there is a system in place for providing 24 hour cover to access the code-break for a clinical trial (as per Section 9.8 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)
	Approvals (Regulatory Green Light)					
29	**For clinical trials where the Trust acts as a Sponsor, does the Pharmacy have a procedure in place to ensure that all of the required approvals and documentation are in place before IMP can be released from Pharmacy?**					Investigational medicinal products should remain under the control of the sponsor until after completion of a two-step procedure: certification by the Qualified Person; and release by the sponsor for use in a clinical trial following fulfillment of the requirements of Article 9 (Commencement of a clinical trial) of Directive 2001/20/EC. Both steps should be recorded3 and retained in the relevant trial files held by or on behalf of the sponsor (as per Article 43 of Annex 13, accessed from:

#	Details	Yes	No	N/A	Don't know	Comments
						http://ec.europa.eu/health/files/eudralex/vol-4/2009_06_annex13.pdf) **What is meant by the terms Qualified Person (QP) release and Qualified Person certification?** The terms QP release and QP certification, are often (incorrectly) used interchangeably. However the responsibilities for release and certification are defined in clinical trials legislation. EUGMP Annex 13, Paragraph 44 requires IMPs remain under the control of the sponsor until after completion of a two-step procedure: Certification by the QP; and release following fulfillment of the requirements of Article 9 (commencement of a clinical trial) of 2001/20/EC. The QP has a legal responsibility as laid out in Article 13 of 2001/20/EC to ensure that the IMP has been manufactured in accordance with EU GMP and meets the conditions of the clinical trial authorisation and the product specification file (PSF). In certifying a batch against the PSF, investigational medicinal product dossier or the clinical trial authorisation (CTA) the QP is providing certification, which has been known previously as the technical green light. Release of IMPs for use in a clinical trial should not occur until after the QP has certified the batch(s). Under Article 9 of 2001/20/EC, the sponsor may not start a clinical trial until the clinical trial

#	Details	Yes	No	N/A	Don't know	Comments
						authorisation has been granted for the trial and all conditions of the authorisation have been met; and an Ethics Committee positive opinion has been granted and each trial site has been approved. The process for ensuring that the appropriate approvals are in place has been known previously as the regulatory green light. In practice, although the QP certification and regulatory approval processes may be run in parallel, the sponsor is responsible for ensuring both steps are completed prior to the release of IMPs for use in a clinical trial. The QP certification must be provided by a QP named on the MIAIMP licence specified in the clinical trials authorisation as responsible for the manufacturing and importation of the IMP. The regulatory green light release may be delegated by the sponsor to the QP, regulatory affairs or trial manager. However the sponsor retains legal responsibility. (MHRA Guidance – Accessed from: http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodClinicalPractice/Frequentlyaskedquestions/index.htm#IM13)
30	**Does the Pharmacy have procedures in place to document that, prior to the commencement of a clinical trial and the dispensing of any IMPs, they are satisfied that clinical trials have:** • **Appropriate regulatory documentation in place i.e., clinical trial authorization**					**Confirmation that the trial has received permission to take place in the Trust under research governance arrangements** The pharmacy coordinator will need to liaise with the Trust R&D to confirm that the trial has received permission to take place in the Trust under research governance arrangements. He/she would also

#	Details	Yes	No	N/A	Don't know	Comments
	• **Been given a favourable opinion by the appropriate Research Ethics Committee(s)** • **Been approved by the local R&D Department** In addition, the pharmacy department must be in receipt of the final copy of the protocol and any amendments and the latest version of the Investigators Brochure (IB) prior to dispensing any IMP (as per Section 10.1 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					need to be provided with copies of the relevant documents about the trial and any subsequent amendments to documents including the protocol, and copy these on as appropriate to other staff involved, to support compliance with the principles of Good Clinical Practice in the trial. (DoH/MRC – Management Issues for Clinical Trials, 2004 – Accessed from: http://www.ct-toolkit.ac.uk/_db/_documents/Hospitals.pdf)
31	**Does Pharmacy request the documentation or confirmation of QP certification for each batch of IMP?**					**Is it necessary for a pharmacy to obtain QP certification documents when receiving clinical trial stock?** There is often confusion between IMP release and QP certification – those managing IMP should be clear on the distinction between these two processes, as the answer differs. QP certification is the process whereby the QP certifies that the prepared IMP is both manufactured to EU GMP standards and that the product has been assembled as requested and approved in the CTA. Release is defined as approval to ship IMP to a site when all the required approvals (as defined in Article 9 of 2001/20/EC) are in

#	Details	Yes	No	N/A	Don't know	Comments
						place and release should only happen after QP certification has been achieved for that batch. It is normally expected that the pharmacy has the documentation of QP certification for each batch of IMP If the NHS trust is sponsoring the trial, the responsibility for technical release may be contracted out to a contract manufacturing organisation as defined in a technical agreement. In such cases, the trust pharmacy only needs confirmation by the sponsor or sponsor's representative that QP certification has taken place and the product is ready for use. If the pharmacy is acting on behalf of a host organisation, they must have assurance from the sponsor that QP certification has been performed. Such assurance may be a copy of the QP certification document or a letter or email confirmation from the sponsor. (MHRA Guidance – Accessed from: http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodClinicalPractice/Frequentlyaskedquestions/index.htm#IM13)
32	**Do Pharmacy implement a study-specific filing system for the essential clinical trial documents (e.g., a 'Pharmacy File') prior to the start of each clinical trial?**					The relevant pharmacist should hold a copy of all trial protocols, including codes and all patient information sheets for studies being undertaken in either the hospital or community services. (As per Section 8.2.1 of The Safe and Secure Handling of Medicines (2005) – Accessed

#	Details	Yes	No	N/A	Don't know	Comments
						from: http://www.rpharms.com/support-pdfs/safsechandmeds.pdf)
	IMP Management (Pharmacy Policies & Procedures)					
33	**Does the pharmacy have written clinical trials standard operating procedures (SOPs) to cover the following procedures?** • Receipt and recording of the safe delivery of IMPs • Safe handling and storage of IMPs • Code breaking • Preparation and dispensing of IMPs in accordance with professional standards (including dispensing against an appropriate prescription, maintaining drug accountability records and ensuring that all IMPs are labeled with the appropriate pharmacy label) • Return and disposal of unused IMPs • Reconciliation of IMPs • Maintaining a Pharmacy Study file • Training of clinical trial pharmacy staff • Archiving of clinical trials documentation (as per Section 11.1 of the Pharmacy Practice Guide, 2005 – Accessed from:					

#	Details	Yes	No	N/A	Don't know	Comments
	http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					
34	**Are the Pharmacy SOPs authorized and reviewed at regular intervals (e.g., annually)?** (as per Section 11.1 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					SOPs and other documents produced by pharmacy should be version controlled to ensure that the correct documents are used. Superseded documents should not be destroyed (as per Section 11.1 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)
35	**Does Pharmacy keep accurate records with sufficient information to provide a full audit trail from the receipt of the IMPs to their removal from site or destruction?** (as per Section 11.2 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					**Common inspection findings**: • Insufficient records for the chain of custody (from purchase to destruction) for marketed products used in clinical trials • http://www.ct-toolkit.ac.uk/_db/_documents/mhra_inspection_guide_311006.doc **Pharmacy Records and IMP Reconciliation** Records should be kept of receipt, dispensing, issue, administration, and disposal of all medicines to facilitate reconciliation. Pharmacies should create standard operating procedures (SOPs) for the receipt,

#	Details	Yes	No	N/A	Don't know	Comments
						dispensing, issue, and disposal of clinical trial medicines. (E.g. following the guidelines prepared by the Institute for Clinical Research (www.acrpi.com) booklet, SOPs and Checklists for Pharmacy Personnel.) (As per Section 8.2.4 of The Safe and Secure Handling of Medicines (2005) – Accessed from: http://www.rpharms.com/support-pdfs/safsechandmeds.pdf) The pharmacy should be involved in the reconciliation of medicines returned by trial patients and the disposal of unused medication. Guidance can be obtained from the Regional Quality Assurance pharmacists' document on Waste Disposal. (DoH/MRC – Management Issues for Clinical Trials, 2004 – Accessed from: http://www.ct-toolkit.ac.uk/_db/_documents/Hospitals.pdf) **Documentation and Records** The clinical trials pharmacist/ pharmacy coordinator will need to ensure that appropriate records of dispensing and detailed drug accountability are kept in the pharmacy and appropriate arrangements made for clinical trial documentation to be retained in

#	Details	Yes	No	N/A	Don't know	Comments
						the pharmacy for the period as may be specified in the protocol. Storage after that time is the responsibility of the sponsor. It is good practice for records of pharmacy storage conditions for the medicines involved in the trial to be kept. Where agreed, randomisation of in-house clinical trials can be undertaken by pharmacists with access to appropriate statistical input. The randomisation codes would be held by the pharmacy, and arrangements would need to be made to allow for codes to be broken outside of normal pharmacy working hours according to the specified criteria. Records of any such intervention would need to be made in the relevant trial documentation. As with other quality systems, all processes (including dispensing and agreed arrangements for administration to inpatients on the wards) will be described in standard operating procedures for the specific trial, which would be regularly reviewed. (DoH/MRC – Management Issues for Clinical Trials, 2004 – Accessed from: http://www.ct-toolkit.ac.uk/_db/_documents/Hospitals.pdf)
36	**Are the Pharmacy clinical trial records regularly audited by pharmacy staff, with reconciliation?** (As per Section 8.2.4.2 of The Safe and Secure Handling of Medicines (2005) –					Refer to Pharmacy SOP CT018P **Audit**

#	Details	Yes	No	N/A	Don't know	Comments
	Accessed from: http://www.rpharms.com/support-pdfs/safsechandmeds.pdf)					As with other preparative services there is a need for regular internal audit of the processes. This would include all aspects of the clinical trials process from receipt of the submission in pharmacy to the administration of the product to the patient. Pharmacies and their records may be inspected as part of the MHRA's Good Clinical Practice inspections. Licensed manufacturing units will be subjected to Good Manufacturing Practice audit by the MHRA inspectors. (DoH/MRC – Management Issues for Clinical Trials, 2004 – Accessed from: http://www.ct-toolkit.ac.uk/_db/_documents/Hospitals.pdf)
37	**Does Pharmacy maintain the following documentation relating to IMP manufacture and shipment (where appropriate)?** • Original prescription • randomisation code and code break • drug accountability or dispensing records (including any marketed authorised products used as IMPs, comparator or adjuvant therapy) and destruction records • production worksheet or batch sheet • evidence that QP certification has been performed					**What documentation needs to be maintained relating to IMP manufacture and shipment?** SI 2004/1031 (as amended) defines the principles of GCP (Schedule 1 Part 2.9) without defining what records to maintain. One of the objectives of GCP is to enable trial data to be accurately reconstructed and reported. IMP records must be maintained to demonstrate adherence to the trial protocol and credibility and integrity of the data. Such records may include but are not limited to the following: • Original prescription • randomisation code and code break

#	Details	Yes	No	N/A	Don't know	Comments
	• storage temperature records including calibration records of temperature monitors • transit temperature records • re-labelling records • validation documents for electronic prescribing systems including validation document for prescribing module or protocol set-up within the electronic prescribing system.					• drug accountability or dispensing records (including any marketed authorised products used as IMPs, comparator or adjuvant therapy) and destruction records • production worksheet or batch sheet • evidence that QP certification has been performed • storage temperature records including calibration records of temperature monitors • transit temperature records • re-labelling records • validation documents for electronic prescribing systems including validation document for prescribing module or protocol set-up within the electronic prescribing system. The list is not exhaustive, but the concept is clear: Any factors that could affect the integrity of the data relating to the IMP should be recorded, monitored and maintained. The principle applies irrespective of the storage medium. (MHRA Guidance – Accessed from: http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodC

#	Details	Yes	No	N/A	Don't know	Comments
						linicalPractice/Frequentlyaskedquestions/index.htm#IM13)
38	**Are IMPs always labeled with the patient's name and date dispensed?** (as per Section 11.4 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					**IMP Labelling** Investigational medicinal products for administration to inpatients should be labelled in accordance with labelling requirements (see document "Labelling of investigational medicinal products"). (DoH/MRC – Management Issues for Clinical Trials, 2004 – Accessed from: http://www.ct-toolkit.ac.uk/_db/_documents/Hospitals.pdf) **Note on Labelling operations** Adding patient specific labelling to a marketed product is part of dispensing in supplying to a patient. However it is an assembly operation where labels are prepared and attached in bulk in advance. There appear to be the following options associated with such labelling in advance: • Where a trial involves a series of separate dosage changes it would seem preferable to repack and label in an IMP manufacturing unit to provide for Good Clinical Practice. • Where a trial only uses a consistent dosage through out the trial, and there are large numbers of patients in the trial at a single centre, it would be efficient to pre-assemble

#	Details	Yes	No	N/A	Don't know	Comments
						labelled supplies in the hospital (or health centre) making use of the exemption provisions of Regulation 37, leaving the individual patient details to be added as a dispensing operation. (DoH/MRC – Labelling of IMPs, 2004 – Accessed from: http://www.ct-toolkit.ac.uk/_db/_documents/labelling.pdf)
39	**Is the patient identity removed before it is returned to the sponsor?** (as per Section 11.4 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					
	Are clinical trial participants counseled on the correct use of the IMP in addition to any written information, which is provided e.g., clinical trial patient information sheet or the patient information leaflet (PIL)? (as per Section 11.5 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					
40	**Are Pharmacy staff aware of (and trained on) the reporting requirements and procedures for possible adverse events**					

#	Details	Yes	No	N/A	Don't know	Comments
	experienced by patients in a clinical trial? (as per Section 11.6 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839) As per Regulations 32 and 33 of SI 2004/1031 as amended – Accessed from: http://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf)					
	Clinical Trial Prescriptions					
41	**Are all IMPs prescribed on a hospital drug chart or a prescription form which is signed by a prescriber who is recognized as participating in the clinical trial?** (as per Section 12.1 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					Only qualified and registered medical practitioners and health care professionals who are supplementary prescribers* can prescribe IMPs. The IMPs must be prescribed on a hospital drug chart or an a prescription form which is signed by a prescriber who is recognized as participating in the clinical trial (as per Section 12.1 of the Pharmacy Practice Guide, 2005) *A supplementary prescriber can prescribe unlicensed medicines if part of a clinical trial. If a supplementary prescriber prescribes for a clinical trial, then the pharmacy department should be provided with written confirmation of this arrangement which is signed by the local investigator and the sponsor. This document should be included in the pharmacy study file – source: http://www.mhra.gov.uk/Howweregulate/Medicines/Availabilityprescribingsellingandsupplyingofmedicines/ExemptionsfromMedicinesActrestrictions/Supplementaryprescribing/index.htm Further guidance can be found at:

#	Details	Yes	No	N/A	Don't know	Comments
						http://www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Prescriptions/TheNon-MedicalPrescribingProgramme/Supplementaryprescribing/index.htm
42	**Are study-specific clinical trial prescription forms used to facilitate the prompt identification of the clinical trial and dispensing procedures and to reduce the risk of dispensing errors?** (as per Section 12.2 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					**Clinical trial medication should be supplied against an appropriate prescription form.** There are advantages to the use of trial specific directions or prescription forms agreed between the trial investigators and the pharmacy; these would carry the title of the study and unique trial reference number (eg EUDRAct number). (DoH/MRC – Management Issues for Clinical Trials, 2004 – Accessed from: http://www.ct-toolkit.ac.uk/_db/_documents/Hospitals.pdf)
43	**Do prescriptions for IMPs clearly identify the clinical trial, the subject and medication required?** (as per Section 12.3 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					
44	**Are patient information sheets (part of the informed consent package) made available when medicines are given as part of a clinical trial?** (As per Section 8.2.3.1 of The Safe and Secure Handling of Medicines (2005) – Accessed from: http://www.rpharms.com/support-pdfs/safsechandmeds.pdf)					

#	Details	Yes	No	N/A	Don't know	Comments
45	**When an IMP is prescribed for an in-patient, is it standard practice to ensure that the medicine chart clearly identifies the clinical trial and the IMP and include the words "clinical trial"?** (as per Section 12.3 of the Pharmacy Practice Guide, 2005 – Accessed from: http://www.icr-global.org/EasySiteWeb/GatewayLink.aspx?alId=1839)					
	Complaints, Recalls and Quarantine					
46	**Does pharmacy have documented procedures (SOPs) describing the process(es) to follow when dealing with IMP complaints, recalls and/or quarantine?** (as per Articles 48 to 52 of Annex 13 – Accessed from: http://ec.europa.eu/health/files/eudralex/vol-4/2009_06_annex13.pdf) (as per Sections 5.1, 5.14.4 of ICH GCP – Accessed from: http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf)					
47	**If so, does the SOP cover the following?** • Procedure for triaging IMP complaints • IMP audit trail system that will enable recall • Dealing with drug alerts from the MHRA Defective					

#	Details	Yes	No	N/A	Don't know	Comments
	Medicines Report Centre • Dealing with drug recalls initiated by a trial Sponsor • Informing Investigators and Clinical Trial participants • Recall and quarantine of IMP					
48	**Does Pharmacy have a validated computer system or paper system that will enable efficient and effective recall of IMP?**					
49	**If an IMP recall procedure exists, is it tested on a regular basis (e.g., annually)?**					
50	**Is there documented evidence that the IMP Recall system has been tested?**					
51	**Does Pharmacy have a specified secure area for storage of quarantined IMP?**					
	Risk Management					
52	**Are risk assessments carried out in connection with the drug products and procedures (including the use of delivery devices) to determine potential risks to patients and staff?** (As per Section 8.3.1.1 of The Safe and Secure Handling of Medicines (2005) – Accessed from:					

#	Details	Yes	No	N/A	Don't know	Comments
	http://www.rpharms.com/support-pdfs/safsechandmeds.pdf)					
53	**Are risk management procedures in place to minimise the risks from trial medicines or procedures to patients and staff?** (As per Section 8.3.1.1 of The Safe and Secure Handling of Medicines (2005) – Accessed from: http://www.rpharms.com/support-pdfs/safsechandmeds.pdf)					

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ICH GCP - International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use: Guideline For Good Clinical Practice E6(R1)	http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf Accessed on 4th August 2011
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The Marketed Products Directive (2001/83/EC as amended) - Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use	http://ec.europa.eu/health/files/eudralex/vol-1/dir_2001_83_cons2009/2001_83_cons2009_en.pdf Accessed on 17th August 2011
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