1. Section	**Variable**	**Information**	**Notes**	**Direct relevance to SACT preparation in Pharmacy?**	**National standard?**
1	**Reference**	ASHP Guidelines on Compounding Sterile Preparations		Yes	No
1.1	Publication I.D.	Am J Health-Syst Pharm. 2014; 71:145-66			
1.2	Date	2014			
2	**Country**	USA			
3	**Standard implemented**	ASHP Guidelines on Compounding Sterile Preparations			
3.1	Type	Guideline			
3.2	Headings	Legal and Regulatory Considerations Accreditation Considerations Other Compounding-Related Guidelines Facility requirements *Design and Functionality Requirements* *Architecture* *Buffer areas* *Renovations* *Cleaning* *Pharmacy Compounding Devices* *Monitoring* *Expiration and beyond use* *Risk level classification* *Point of care activation* *Ampoules, single and multi-dose units* *Batch Compounding and Sterility Testing* Outsourcing Personnel *Responsibilities* P*ackaging and labelling* *Storage* *Transport*			

		Control and oversight of IV solons *Redispersing* *Handling* *Specialty preparations* *Compounding Competency* *Testing (media fill and fingertip)* *SOP development* *Quality Assurance Program*			
3.3	Reference protocol standards	Harmonisation between previous ASHP guidelines with USP 797			
3.4	Reference source (if applicable)	https://www.usp.org/compounding/general-chapter-797			
4	**Responsible authority**				
4.1	Region of authority	USA			
4.2	Author	American Society of Health System Pharmacists			
4.3	Drafting role	None			
4.4	Implementation role	Document only for guidance, no direct enforcement			
5	**Audit process**				
5.1	Internal inspection				
5.1.1	Internal inspection process	To be set out in local plans and standards Carried out by compounding personnel or qualified certifier where needed			

5.1.2	Internal inspection schedule	**Environmental monitoring** At the commissioning and certification of new facilities and equipment. Every six months during routine recertification of equipment and facilities. After any facility or equipment maintenance, including construction or remodelling of adjacent departments or work on shared air handlers. At any point when problems are identified with products, preparations, or employee technique or if a CSP is suspected to be the source of a patient infection. Daily temp checks Every 6 month tests for airborne particles (viable and nonviable) **Storage areas** - at least a monthly basis			
5.2	External inspection	None specified in guidelines			
5.2.1	External inspection process				
5.2.2	External inspection schedule				
5.3	Legal process for inspection				
5.4	Process for discrepancies	None mentioned in guidelines			

2. Section	**Variable**	**Information**			
1	**Reference**				
1.1	Publication I.D.	NCCP oncology medication safety review		No	No
1.2	Date	Jan-14			
2	**Country**	Ireland			
3	**Standard implemented**				
3.1	Type	Review			
3.2	Headings	Governance And Service Configuration Risk Management Built Environment, Activity And Equipment Staffing Staff Training Policies And Guidelines Information For Patients And Carers Treatment Planning And Clinical Assessment Chemotherapy Protocols Chemotherapy Ordering And Prescribing Chemotherapy Orders And Prescription Checking Administration And Monitoring Of Chemotherapy Management Of Unscheduled Care Intrathecal Chemotherapy Pharmacy – Chemotherapy Preparation, Labelling And Record Keeping Handling, Disposal And Storage Of Cytotoxic Drugs			
3.3	Reference protocol standards	**NO ASEPTIC QA REFERENCE** HIQA's National Standards for Safer Better Healthcare			

3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	Ireland			
4.2	Author	NCCP			
4.3	Drafting role	NCCP subsection review of standards across country			
4.4	Implementation role	n/a			
5	**Audit process**	**None relevant**			
5.1	Internal inspection				
5.1.1	Internal inspection process				
5.1.2	Internal inspection schedule				
5.2	External inspection				
5.2.1	External inspection process				
5.2.2	External inspection schedule				

5.3	Legal process for inspection				
5.4	Process for discrepancies				
3. Section	**Variable**				
1	**Reference**			Yes	No
1.1	Publication I.D.	HPAI National Guidelines for Aseptic Compounding in Irish Hospital Pharmacy Practice			
1.2	Date	2013			
2	**Country**	Ireland			
3	**Standard implemented**				
3.1	Type	Guideline			
3.2	Headings	Same as PIC/S			
3.3	Reference protocol standards				
3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	Ireland			

4.2	Author	Hospital Pharmacists Association of Ireland			
4.3	Drafting role	Drafted in conjunction with HIQA, PIC/S chosen as most suitable guidance			
4.4	Implementation role	Guidelines only			
5	**Audit process**				
5.1	Internal inspection	See PIC/S			
5.1.1	Internal inspection process				
5.1.2	Internal inspection schedule				
5.2	External inspection	Guidelines only			
5.2.1	External inspection process				
5.2.2	External inspection schedule				
5.3	Legal process for inspection				
5.4	Process for discrepancies				

4. Section	**Variable**	**Information**			
1	**Reference**				
1.1	Publication I.D.	HSE Guideline on the Safe Handling of Cytotoxic Drugs 2022		Yes	Yes
1.2	Date	Feb-22			
2	**Country**	Ireland			
3	**Standard implemented**				
3.1	Type	Guideline			
3.2	Headings	Risk assessment process Communicate and Notification of Risk Monitoring and periodic review Training Health surveillance and record keeping Health monitoring Incident management Roles and responsibilities Initiation Development of PPPG Governance and approval Communication and dissemination Implementation Monitoring, audit and evaluation Revision/Update			
3.3	Reference protocol standards	**NO ASEPTIC QA REFERENCE** Safety, Health and Welfare at Work Act,2005 · Safety, Health and Welfare at Work (Reporting of Accidents and Dangerous Occurrences) Regulations, 2016 · Safety, Health and Welfare at Work (General Application) Regulations, 2007 with particular			

		reference to: o Chapter 1 of Part 2 – Workplace o Chapter 2 of Part 2 Use of Work Equipment o Chapter 3 of Part 2 - Personal Protective Equipment o Chapter 1 of Part 6: Protection of Children and Young Persons o Chapter 2 of Part 6 - Protection of Pregnant, Post Natal and Breastfeeding Employees Safety, Health and Welfare at Work (Carcinogens) Regulations, 2001 and amendment 2015 and 2019 Regulations 2020 Code of Practice for the Safety, Health and Welfare at Work (Chemical Agents) Regulations (2001-2015) and the Safety, Health and Welfare at Work (Carcinogens) Regulations (2001-2019) CLP Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures and amendment Regulations Safety, Health and Welfare at Work (Carcinogens) Regulations, 2001 and amendment Regulations			
3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	Ireland			
4.2	Author	HSE			
4.3	Drafting role	Formed PPG development group to review literature and report findings in form of guidelines			
4.4	Implementation role	Provide guideline for local managers to assess implementation			
5	**Audit process**				

5.1	Internal inspection				
5.1.1	Internal inspection process	Managers use provided reference to assess implementation of guidelines Must maintain physical evidence of same			
5.1.2	Internal inspection schedule	None mentioned			
5.2	External inspection				
5.2.1	External inspection process	Audited at national level			
5.2.2	External inspection schedule	"Periodically"			
5.3	Legal process for inspection	None mentioned			
5.4	Process for discrepancies	None mentioned			
5. Section	**Variable**	**Information**			
1	**Reference**				
1.1	Publication I.D.	HPRA Guide to Clinical Trials Conducted under the Clinical Trials Regulation (CTR) in Ireland		No	Yes
1.2	Date	Jan-22			

2	**Country**	Ireland			
3	**Standard implemented**				
3.1	Type	Guideline			
3.2	Headings	Introduction Clinical trials under CTR Implementation of CTR in Ireland Safety reporting Supervision Archiving Appeals **GCP inspections** Manufacture and/or importation **Enforcement**			
3.3	Reference protocol standards	EU Clinical Trial Regulation (Regulation No 536/2014 (CTR)			
3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	Ireland			
4.2	Author	HPRA			
4.3	Drafting role	Full			
4.4	Implementation role	HPRA is the responsible body for enforcement of the CTR and national legislation pertaining to clinical trials in Ireland and may prosecute for any offences committed.			

5	**Audit process**				
5.1	Internal inspection				
5.1.1	Internal inspection process	Logs of SUSARs, ADRs available to HPRA Annual safety report to HPRA			
5.1.2	Internal inspection schedule	None mentioned			
5.2	External inspection				
5.2.1	External inspection process	Notification 4-6 weeks in advance Inspection plan 1-2 weeks in advance Inspection (3-5 days) - Legal/admin and organisational (e.g personnel/facilities) Report issued 21 days after inspection Inspected response 2-3 weeks Response review Close out letter issued Note: EMA inspection same steps but possibly different timelines HPRA inspects hospitals Begin in 2023 and will be conducted using a risk-based approach.			
5.2.2	External inspection schedule	None mentioned			
5.3	Legal process for inspection	Regulation (EU) No 182/2011 of the European Parliament and of the Council			

5.4	Process for discrepancies	referred to the HPRA's Compliance Regulatory Group (CRG) for consideration. The CRG is a cross- functional group chaired by the Director of Compliance, and for GCP matters would typically be attended by the Inspection Section Manager, GCP/PV Inspection Manager and relevant personnel from other relevant departments within the HPRA. The group agree on the classification of the serious deficiencies identified and consider if any further regulatory action may need to be proposed. Response issued within 21 days			
6. Section	**Variable**	**Information**			
1	**Reference**				
1.1	Publication I.D.	REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC		No	Regional guidance
1.2	Date	May-14			
2	**Country**	EU			
3	**Standard implemented**				
3.1	Type	Regulation			
3.2	Headings	GENERAL PROVISIONS AUTHORISATION PROCEDURE FOR A CLINICAL TRIAL AUTHORISATION PROCEDURE FOR A SUBSTANTIAL MODIFICATION OF A CLINICAL TRIAL APPLICATION DOSSIER PROTECTION OF SUBJECTS AND INFORMED CONSENT START, END, TEMPORARY HALT, AND EARLY TERMINATION OF A CLINICAL TRIAL SAFETY REPORTING IN THE CONTEXT OF A CLINICAL TRIAL CONDUCT OF A CLINICAL TRIAL, SUPERVISION BY THE SPONSOR,			

		TRAINING AND EXPERIENCE, AUXILIARY MEDICINAL PRODUCTS MANUFACTURING AND IMPORT OF INVESTIGATIONAL MEDICINAL PRODUCTS AND AUXILIARY MEDICINAL PRODUCTS LABELLING SPONSORS DAMAGE COMPENSATION SUPERVISION BY MEMBER STATES, UNION INSPECTIONS AND CONTROLS IT INSFRASTRUCTURE COOPERATION BETWEEN MEMBER STATES FEES IMPLEMENTING ACTS AND DELEGATED ACTS MISCELLANEOUS PRVISIONS FINAL PROVISSIONS			
3.3	Reference protocol standards	Repealing and replacing Directive 2001/20/EC			
3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	EU			
4.2	Author	EC			
4.3	Drafting role				
4.4	Implementation role				
5	Audit process	SEE HPRA implementation of same			

5.1	Internal inspection				
5.1.1	Internal inspection process				
5.1.2	Internal inspection schedule				
5.2	External inspection				
5.2.1	External inspection process				
5.2.2	External inspection schedule				
5.3	Legal process for inspection				
5.4	Process for discrepancies				
7. Section	**Variable**	**Information**			
1	**Reference**				
1.1	Publication I.D.	Royal Pharmaceutical Society Quality Assurance of Aseptic Preparation Services: Standards		Yes	Yes
1.2	Date	2016			

2	**Country**	UK			
3	**Standard implemented**				
3.1	Type	Standard/Guideline			
3.2	Headings	Introduction Glossary MINIMISING RISK WITH INJECTABLE MEDICINES PRESCRIBING, CLINICAL PHARMACY AND ASEPTIC 24 SERVICES VERIFICATION Management FORMULATION, STABILITY AND SHELF LIFE Facilities and equipment Pharmaceutical quality systems Personnel training and competency assessment Aseptic processing Monitoring Cleaning, sanitisation and biocontamination Starting materials, components and consumables Product approval Storage and distribution Internal and external audit			
3.3	Reference protocol standards	4th edition, updated to better implement EU GMP and ICH quality risk management			
3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	UK			
4.2	Author	RPS			

4.3	Drafting role	Full			
4.4	Implementation role	Guidance document, adherence to standards responsibility of RQA team of NHS			
5	**Audit process**				
5.1	Internal inspection				
5.1.1	Internal inspection process	Need for pre-defined action plan (w/ SOP) detailing timelines and responsible people All areas of aseptic processing audited on regular planned basis Quality review of pharmaceutical quality system Audit to include capacity planning of unit Audit report to be submitted to senior management			
5.1.2	Internal inspection schedule	"Regular planned"			
5.2	External inspection				
5.2.1	External inspection process	External audit should be carried out by the Regional Quality Assurance specialist or any other accredited auditor			
5.2.2	External inspection schedule	Every 12 to 18 months			
5.3	Legal process for inspection	EL (97) 52, letter to dept of health			

5.4	Process for discrepancies'	Internal audit - Assess risk to product quality and decide whether to cease activity. Escalation procedure to be put in place for chief pharmacist to communicate risk to management External: Results made known to trust chief executives Corrective actions made by next audit or earlier if necessary			
8. Section	**Variable**	**Information**			
1	**Reference**				
1.1	Publication I.D.	WHO good manufacturing practices for sterile pharmaceutical products		No	International guidance
1.2	Date	2011			
2	**Country**	International			
3	**Standard implemented**				
3.1	Type	Guidelines			
3.2	Headings	General considerations Quality control Sanitation Manufacture of sterile preparations Sterilization# Terminal sterilization Aseptic processing and sterilization by filtration Isolator technology Blow/fi ll/seal technology Personnel Premises Equipment Finishing of sterile products			

3.3	Reference protocol standards				
3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	N/a			
4.2	Author	WHO			
4.3	Drafting role				
4.4	Implementation role	Handled by national competent authorities			
5	**Audit process**	None mentioned			
5.1	Internal inspection	None mentioned			
5.1.1	Internal inspection process	None mentioned			
5.1.2	Internal inspection schedule	None mentioned			
5.2	External inspection	None mentioned			
5.2.1	External inspection process	None mentioned			

5.2.2	External inspection schedule	None mentioned			
5.3	Legal process for inspection	None mentioned			
5.4	Process for discrepancies				
9. Section	**Variable**	**Information**			
1	**Reference**				
1.1	Publication I.D.	EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines	PIC/S GMP standards are developed in harmony with EU and are "practically identical"	No	EU standard
1.2	Date	2008			
2	**Country**	EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines			
3	**Standard implemented**				
3.1	Type	Guideline			
3.2	Headings	Pharmaceutical Quality System Personnel Premise and Equipment Documentation Production Quality Control Outsourced activities Complaints and Product recall Self inspection Basic requirements for active substances used as starting			

		materials Site Master File Quality Risk Management Note for Guidance on Pharmaceutical Quality System MRA Batch Certificate Template for the "written confirmation" for active substances exported to the European Union for medicinal products for human use Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities Guidelines of 19 March 2015 on the formalised risk assessment for ascertaining the appropriate good manufacturing practice for excipients of medicinal products for human use Template for IMP batch release Reflection paper on Good Manufacturing Practice and Marketing Authorisation Holders			
3.3	Reference protocol standards	Article 47 of Directive 2001/83/EC			
3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	EU			
4.2	Author	EC			
4.3	Drafting role	Commissioned by council of ministers			
4.4	Implementation role	National competent authorities responsible			

5	**Audit process**				
5.1	Internal inspection				
5.1.1	Internal inspection process	None mentioned beyond record keeping, quality control department and responsibilities mentioned w/ regards to manufacturing			
5.1.2	Internal inspection schedule	None mentioned			
5.2	External inspection	None mentioned in standards, handled by EMA and national authorities			
5.2.1	External inspection process				
5.2.2	External inspection schedule				
5.3	Legal process for inspection	Directive 2001/83/EC, mandatory within EEA			
5.4	Process for discrepancies				
10. Section	**Variable**	**Information**			
1	**Reference**				

1.1	Publication I.D.	Resolution CM/Res (2016)2 on good reconstitution practices in health care establishments for medicinal products for parenteral use		Yes	EU standard
1.2	Date	2016			
2	**Country**	EU			
3	**Standard implemented**				
3.1	Type	Resolution			
3.2	Headings	Field of application Definitions **Responsibilities** -Authorities -Healthcare establishment - Risk assessment -Auditing Minimum requirements (standards) for reconstitution Handling the risk of reconstitution in clinical areas - Identification - Assessment - Management -Acceptance -Review			
3.3	Reference protocol standards	Resolution CM/Res AP(2011)			
3.4	Reference source (if applicable)				
4	**Responsible authority**				

4.1	Region of authority	EU			
4.2	Author	EC			
4.3	Drafting role	Developed by Committee of experts as an update to parent resolution to clarify standards for reconstitution			
4.4	Implementation role				
5	**Audit process**				
5.1	Internal inspection				
5.1.1	Internal inspection process	Standards and plan put in place by management Regular risk assessment - if high risk consider reconstituting elsewhere Designated person (preferably pharmacist) with clear mandate and full access to establishment -Approve SOPs - Develop quality management system - Develop parenteral manual			
5.1.2	Internal inspection schedule	Suggested annually			
5.2	External inspection				
5.2.1	External inspection process	None mentioned			
5.2.2	External inspection schedule	None mentioned			

5.3	Legal process for inspection	None mentioned			
5.4	Process for discrepancies	None mentioned			
11. Section	**Variable**	**Information**			
1	**Reference**				
1.1	Publication I.D.	Resolution CM/Res(2016)1 on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients		Yes	EU standard
1.2	Date	2016			
2	**Country**	EU			
3	**Standard implemented**				
3.1	Type	Resolution			

3.2	Headings	Added value of pharmacy preparations and responsibilities of health care professionals Preparation process Product dossier Risk assessment Marketing authorisation Labelling Compliance with pharmacopeial requirements Reconstitution of medicinal products in health care establishments Authorisation for pharmacies or licences for companies making preparations for pharmacies Transparency and safety Communication and information to patients Distribution of pharmacy preparations			
3.3	Reference protocol standards	Update on 2011 version, which was made to harmonise and provide standards			
3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	EU			
4.2	Author	EC			
4.3	Drafting role	Special committee drafted original resolution in response to survey identifying varying standards across EU and no central guidance			
4.4	Implementation role	Set out in resolution, but handled by national authorities			
5	**Audit process**				

5.1	Internal inspection	None mentioned			
5.1.1	Internal inspection process	None mentioned			
5.1.2	Internal inspection schedule				
5.2	External inspection				
5.2.1	External inspection process	Recommends development of national standards by competent authorities. Recommends setup of notification system for reports of safety issues, and authorities should carry out risk-based assessments based on that, No further mention/specification of inspections			
5.2.2	External inspection schedule	None mentioned			
5.3	Legal process for inspection	None mentioned			
5.4	Process for discrepancies	None mentioned			
12. Section	**Variable**	**Information**			
1	**Reference**				
1.1	Publication I.D.	USP General Chapter <797>	Proposed changes included for most up to date version	Yes	Yes

1.2	Date	2021			
2	**Country**	USA			
3	**Standard implemented**				
3.1	Type	Standards document			
3.2	Headings	Scope and introduction PERSONNEL TRAINING AND EVALUATION PERSONAL HYGIENE AND GARBING FACILITIES AND ENGINEERING CONTROLS CERTIFICATION AND RECERTIFICATION MICROBIOLOGICAL AIR AND SURFACE MONITORING CLEANING, DISINFECTING, AND APPLYING SPORICIDAL DISINFECTANTS IN COMPOUNDING AREAS INTRODUCING ITEMS INTO THE Secondary Engineering Controls (SEC) AND Primary Engineering Controls (PEC) EQUIPMENT, SUPPLIES, AND COMPONENTS STERILIZATION AND DEPYROGENATION MASTER FORMULATION AND COMPOUNDING RECORDS RELEASE INSPECTIONS AND TESTING ESTABLISHING BEYOND-USE DATES LABELING USE OF CONVENTIONALLY MANUFACTURED PRODUCTS AS COMPONENTS USE of CSPS as components SOPs QUALITY ASSURANCE AND QUALITY CONTROL CSP HANDLING, STORAGE, PACKAGING, SHIPPING, AND TRANSPORT COMPOUNDING ALLERGENIC EXTRACTS			
3.3	Reference protocol standards	Update to official chapter of 2008			

3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	USA			
4.2	Author	USP			
4.3	Drafting role	USP Compounding Expert Committee is responsible for the development of General Chapter <797>			
4.4	Implementation role	USP has no role in enforcement, assuring compliance with USP standards is the responsibility of regulatory bodies (can be both state and FDA) Some state regulations require full compliance with USP chapter 797, some have indirect references to the chapter, some do not mention the chapter, and some have additional regulations.			
5	**Audit process**				
5.1	Internal inspection				
5.1.1	Internal inspection process	No specific audit process detailed Recommendations: -SOPs and action plans - Designated person to implement and maintain same -Training for all personnel involved in or having direct oversight of the compounding of CSPs initially + every 12 months -Written training programme -aseptic manipulation competency test every 6 months			
5.1.2	Internal inspection schedule				

5.2	External inspection				
5.2.1	External inspection process	Defers to FDA procedure Visit and inspection Inspection of logs/ audits/ quality plan/ risk analysis / training procedures etc. Closeout meeting			
5.2.2	External inspection schedule	None mentioned FDA employs risk-based schedule			
5.3	Legal process for inspection	Section 704 of the FD&C Act			
5.4	Process for discrepancies	FDA: Issued FDA form 483 plus timetable for corrections Allow time (15 days for written response) for response and appropriate changes If not satisfactory, three types of judicial enforcement actions—the seizure of unlawful product; an injunction (usually ordering a firm to cease operations, abide by rigorous conditions or disgorge profits); and criminal prosecution. These actions usually involve companies that have had poor inspection histories; have, in FDA's view, caused a significant risk to public health; or have engaged in fraud or deliberate misconduct. The Department of Justice represents FDA in court.			
13. Section	**Variable**	**Information**	As of this moment, not compendial applicable. Will be in the future once proposed revisions to USP 795 and 797 are made (only becomes compendially applicable when referenced by chapter under 1000, and only to extent it is referred to in those chapters)		

1	**Reference**			Yes	Yes (not compendial active yet)
1.1	Publication I.D.	USP General Chapter <800>			
1.2	Date	2020 (revised)			
2	**Country**				
3	**Standard implemented**				
3.1	Type				
3.2	Headings	Introduction and Scope List of Hazardous Drugs Types of Exposure Responsibilities of Personnel Handling Hazardous Drugs Facilities and Engineering Controls Environmental Quality and Control Personal Protective Equipment 8. Hazard Communication Program Personnel Training Receiving Labelling, Packaging, Transport, and Disposal Dispensing Final Dosage Forms Compounding Administering Deactivating, Decontaminating, Cleaning, and Disinfecting Spill Control Documentation and Standard 0perating Procedures Medical Surveillance			
3.3	Reference protocol standards				

3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	USA			
4.2	Author	USP			
4.3	Drafting role	Full, USP expert committee			
4.4	Implementation role	Informational only			
5	**Audit process**				
5.1	Internal inspection				
5.1.1	Internal inspection process	No specific audit details: 12 monthly review of SOPs by designated person Medical surveillance plan and escalation plan for all personnel handling hazardous drugs			
5.1.2	Internal inspection schedule				
5.2	External inspection				
5.2.1	External inspection process	Defers to FDA procedure Visit and inspection Inspection of logs/ audits/ quality plan/ risk analysis / training procedures etc. Closeout meeting			

5.2.2	External inspection schedule	None mentioned FDA employs risk-based schedule+C310			
5.3	Legal process for inspection	**Section 704 of the FD&C Act**			
5.4	Process for discrepancies	FDA: Issued FDA form 483 plus timetable for corrections Allow time (15 days for written response) for response and appropriate changes If not satisfactory, three types of judicial enforcement actions—the seizure of unlawful product; an injunction (usually ordering a firm to cease operations, abide by rigorous conditions or disgorge profits); and criminal prosecution. These actions usually involve companies that have had poor inspection histories; have, in FDA's view, caused a significant risk to public health; or have engaged in fraud or deliberate misconduct. The Department of Justice represents FDA in court.			
14. Section	**Variable**	**Information**			
1	**Reference**				
1.1	Publication I.D.	Institute for safe medicinal practices Guidelines for Safe Preparation of Compounded Sterile Preparations	Survey posted to assess implementation of best practice in 2020 https://www.ismp.org/resources/ismp-survey-provides-insights-pharmacy-sterile-compounding-systems-and-practices	Yes	No
1.2	Date	2016	More than half of all respondents (57%, n = 361) reported using technologies when compounding sterile preparations		

2	**Country**	USA/international	Nearly three-quarters (74%) of all survey respondents were aware of at least one pharmacy sterile compounding error that had occurred during the past 12 month		
3	**Standard implemented**		the most commonly cited challenge was the inability for a pharmacist to accurately verify prepared CSPs if using an indirect process such as the post-procedure syringe pull-back method. The second most common challenge was associated with meeting USP <797> (*Pharmaceutical Compounding – Sterile Preparations*) and USP <800> (*Hazardous Drugs – Handling in Healthcare Settings*) standards. The ability to properly train both technicians and pharmacists to prepare and/or verify CSPs was listed as the third biggest challenge, followed by the lack of purchasing and utilizing various sterile compounding technologies		
3.1	Type	Guideline document			
3.2	Headings	Order Entry and Verification Drug Inventory Storage Assembling Products and Supplies for Preparation Compounding Drug Conservation Compounding Performed Outside the Pharmacy IV Admixture Service Preparation of Source/Bulk Containers Technology/Automation Used for Compounding CSPs Automated Compounding (Pumping) Systems Quality Control/Final Verification Product Labelling Staff Management			

3.3	Reference protocol standards	Defers to USP <797> for minimum standards, goal of document is to provide guidance on more specific topic of compounding			
3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	International			
4.2	Author	ISMP			
4.3	Drafting role	Summit of medical professionals, resulted in a set of guidelines and safe practices, that were agreed upon by consensus to ensure the safe preparation of CSPs			
4.4	Implementation role	No implementation responsibility, guidance only			
5	**Audit process**	None mentioned			
5.1	Internal inspection				
5.1.1	Internal inspection process				
5.1.2	Internal inspection schedule				
5.2	External inspection				

5.2.1	External inspection process				
5.2.2	External inspection schedule				
5.3	Legal process for inspection				
5.4	Process for discrepancies				
15. Section	**Variable**	**Information**			
1	**Reference**			Yes	International standard
1.1	Publication I.D.	PIC/S GUIDE TO GOOD PRACTICES FOR THE PREPARATION OF MEDICINAL PRODUCTS IN HEALTHCARE ESTABLISHMENTS			
1.2	Date	2014			
2	**Country**	International			
3	**Standard implemented**				
3.1	Type	Guideline document widely used as standard			

3.2	Headings	Quality assurance system Personnel PREMISES AND EQUIPMENT Documentation QUALITY CONTROL Production WORK CONTRACTED OUT COMPLAINTS AND PRODUCT RECALLS SELF AUDITS			
3.3	Reference protocol standards				
3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	International			
4.2	Author	PHARMACEUTICAL INSPECTION CONVENTION PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME			
4.3	Drafting role	Full			
4.4	Implementation role	Guideline only, have inspection capability but national authorities have end responsibility			
5	**Audit process**				
5.1	Internal inspection				

5.1.1	Internal inspection process	The quality assurance system, including personnel matters, premises, equipment, documentation, production, quality control, distribution of the medicinal products, arrangements for dealing with complaints and work contracted out			
5.1.2	Internal inspection schedule	"Regular intervals" Annual self audit plan			
5.2	External inspection				
5.2.1	External inspection process	Organization recommendation, inspection rests with national authorities			
5.2.2	External inspection schedule				
5.3	Legal process for inspection				
5.4	Process for discrepancies				
16. Section	**Variable**	**Information**		**Yes**	**International standard**
1	**Reference**				
1.1	Publication I.D.	PIC/S Guide to Good Manufacturing Practice for Medicinal Products Part 1 and 2			
1.2	Date	2014			
2	**Country**	International			

3	**Standard implemented**				
3.1	Type	Guideline document widely used as standard			
3.2	Headings	Part 1: Pharmaceutical Quality System Personnel Premises and equipment Documentation Production Quality control Outsourced activities Complaints and product recall Self inspection Part 2 Introduction Quality management Personnel Buildings and facilities Process equipment Documentation and records Materials management Production and in-process controls Packaging and identification labelling of APIs and intermediates Storage and distribution Laboratory controls Validation Change control Rejection and re-use of materials Complaints and recalls Contract manufacturers (including laboratories) Agents, brokers, traders, distributors, \\\\\\\\ and relabellers Specific guidance for APIs manufactured by cell culture / fermentation APIs for use in clinical trials			

3.3	Reference protocol standards				
3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	International			
4.2	Report to	PHARMACEUTICAL INSPECTION CONVENTION PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME			
4.3	Drafting role				
4.4	Implementation role	Guideline only, have inspection capability but national authorities have end responsibility			
5	**Audit process**				
5.1	Internal inspection				
5.1.1	Internal inspection process	Based upon risk assessment along with Detected deviations (e.g. monitoring results which are out of specification), Changes, interventions in the environment or Increased workload			
5.1.2	Internal inspection schedule	Yearly tests for classification tests Daily tests for pressure differentials Weekly surface and isolator glove tests Quarterly air samples and particle counts			
5.2	External inspection	Organization recommendation, inspection rests with national authorities			

5.2.1	External inspection process				
5.2.2	External inspection schedule				
5.3	Legal process for inspection				
5.4	Process for discrepancies				
17. Section	**Variable**	**Information**			
1	**Reference**				
1.1	Publication I.D.	National Association of Pharmacy Regulatory Authorities MODEL STANDARDS FOR PHARMACY COMPOUNDING OF HAZARDOUS STERILE PREPARATIONS	Yes	Yes	Yes
1.2	Date	2016			
2	**Country**	Canada			
3	**Standard implemented**				
3.1	Type	Model standards, minimum standards recommended			
3.2	Headings	CORE REQUIREMENTS FOR A STERILE COMPOUNDING SERVICE - personnel, facilities etc PRODUCT AND PREPARATION REQUIREMENTS - dating SOPs, protocols, compounding guidelines etc			

		QUALITY ASSURANCE PROGRAM - quality assurance, verification, documentation			
3.3	Reference protocol standards	Adapted from standards from Ordre des pharmaciens du Quebec, which are based on USP 797			
3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	Canada			
4.2	Author	National Association of Pharmacy Regulatory Authoritie			
4.3	Drafting role	Adapted from standards from Ordre des pharmaciens du Quebec, which are based on USP 797. USP 800 also considered. Developed by NAPRA ad hoc Committee on Pharmacy Compounding.			
4.5	Implementation role	Implementation under the authority of the respective provincial, territorial or Canadian Armed Forces pharmacy regulatory bodies. These bodies each establish their own process for the implementation of the standards in their jurisdictions.			
5	**Audit process**				
5.1	Internal inspection				
5.1.1	Internal inspection process	Training and competency (theoretical and practical tests (every 6 months high risk, annual other and upon entry) Glove fingertip test (every 6 months high risk, annually other) Media fill test (annually) Clean rooms (every 6 months)			

5.1.2	Internal inspection schedule	See above			
5.2	External inspection	None mentioned, responsibility of regional pharmacy bodies			
5.2.1	External inspection process				
5.2.2	External inspection schedule				
5.3	Legal process for inspection	Food and Drugs Act and the Controlled Drugs and Substances Act Canada			
5.4	Process for discrepancies				
18. Section	**Variable**	**Information**			
1	**Reference**				
1.1	Publication I.D.	National Association of Pharmacy Regulatory Authorities MODEL STANDARDS FOR PHARMACY COMPOUNDING OF NON-HAZARDOUS STERILE PREPARATIONS	Yes	No (hazardous guide more relevant)	Yes
1.2	Date	2016	Exact same as hazardous standards other than lacking details for safe handling and storage		
2	**Country**	Canada			
3	**Standard implemented**				

3.1	Type	Model standards, minimum standards recommended			
3.2	Headings	CORE REQUIREMENTS FOR A STERILE COMPOUNDING SERVICE - personnel, facilities etc PRODUCT AND PREPARATION REQUIREMENTS - dating SOPs, protocols, compounding guidelines etc QUALITY ASSURANCE PROGRAM - quality assurance, verification, documentation			
3.3	Reference protocol standards	Adapted from standards from Ordre des pharmaciens du Quebec, which are based on USP 797			
3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	Canada			
4.2	Report to	National Association of Pharmacy Regulatory Authority			
4.3	Governing structure				
4.4	Drafting role	Adapted from standards from Ordre des pharmaciens du Quebec, which are based on USP 797. USP 800 also considered. Developed by NAPRA ad hoc Committee on Pharmacy Compounding.			
4.5	Implementation role	Implementation under the authority of the respective provincial, territorial or Canadian Armed Forces pharmacy regulatory bodies. These bodies each establish their own process for the implementation of the standards in their jurisdictions.			
5	**Audit process**				

5.1	Internal inspection				
5.1.1	Internal inspection process	Training and competency (theoretical and practical tests (every 6 months high risk, annual other and upon entry) Glove fingertip test (every 6 months high risk, annually other) Media fill test (annually) Clean rooms (every 6 months)			
5.1.2	Internal inspection schedule	See above			
5.2	External inspection	None mentioned, responsibility of regional pharmacy bodies			
5.2.1	External inspection process				
5.2.2	External inspection schedule				
5.3	Legal process for inspection	Food and Drugs Act and the Controlled Drugs and Substances Act Canada			
5.4	Process for discrepancies				
19. Section	**Variable**	**Information**			
1	**Reference**		Endorse USP 800 (extracted) NIOSH alert (extracted) and oncology nursing society (not relevant)		

1.1	Publication I.D.	American Society of Clinical oncology Standards for Safe Handling of Hazardous Drugs	Although the ASCO standards differ in some ways from the USP 800 standards, existing standards are largely endorsed by ASCO	Yes	No
1.2	Date	2019			
2	**Country**	USA			
3	**Standard implemented**				
3.1	Type	Standards, not official but rather additive to USP 800			
3.2	Headings	Endorsement of existing standards Clarifications: medical surveillance closed system transfer devices external ventilation of containment secondary engineering controls or containment segregated compounding areas alternative duties. (for pregnant, breastfeeding or attempting to conceive)			
3.3	Reference protocol standards	Endorse USP 800 NIOSH alert and oncology nursing society			
3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	USA			
4.2	Author	American Society of Clinical oncology			

4.3	Drafting role	An Expert Panel was convened to develop standards for the safe handling of hazardous oncology drugs based on a systematic review of the literature.			
4.4	Implementation role	Recommendations			
5	**Audit process**	None mentioned			
5.1	Internal inspection				
5.1.1	Internal inspection process				
5.1.2	Internal inspection schedule				
5.2	External inspection				
5.2.1	External inspection process				
5.2.2	External inspection schedule				
5.3	Legal process for inspection				
5.4	Process for discrepancies				

20. Section	**Variable**	**Information**	MHRA responsible for hospital pharmacy aseptic dispensing facilities operating under a 'Specials' manufacturing licence.	**No**	**Yes**
1	**Reference**		Recommended in key "Transforming NHS pharmacy aseptic services" to be more transparent with findings, as they can impose more statutory penalties than SPS inspections		
1.1	Publication I.D.	MHRA Guidance for Specials Manufacturers	The document includes guidance on the appropriate standards for the manufacture of aseptically prepared products under an MS licence using essentially closed systems. However, it is important to recognise that all aseptically prepared products where open systems are used, should be manufactured in accordance with the standards outlined in the EU Guide, specifically Annex 1.		Yes
1.2	Date	Jan-21			
2	**Country**	UK			
3	**Standard implemented**				
3.1	Type	Regulatory document providing guidance			
3.2	Headings	Quality Management Personnel Premises and equipment Documentation Production Quality Control Contract Manufacture and Analysis Complaints and Product Recall Self Inspection Distribution and storage Computerised Systems			

3.3	Reference protocol standards	n/a			
3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	UK			
4.2	Author	Medicines and healthcare products regulatory agency			
4.3	Drafting role	Full			
4.4	Implementation role	Authority for inspection and assessment			
5	**Audit process**				
5.1	Internal inspection				
5.1.1	Internal inspection process	"No topics identified at this time" Monitoring requirements same as EU GMP annex 1			
5.1.2	Internal inspection schedule				

5.2	External inspection	Pharmacies exempt if operating under section 10(1)a exemption Prepared by or under the supervision of a pharmacist in a registered pharmacy, a hospital, a care home service or a health centre. In accordance with a medical prescription given by a practitioner. For a specific patient. Under authority of General Pharmaceutical Council -Unannounced -uses decision making framework --The governance arrangements safeguard the health, safety and wellbeing of patients and the public --Staff are empowered and competent to safeguard the health, safety and wellbeing of patients and the public --The environment and condition of the premises from which pharmacy services are provided, and any associated premises, safeguard the health, safety and wellbeing of patients and the public --The way in which pharmacy services, including the management of medicines and medical devices, are delivered safeguards the health, safety and wellbeing of patients and the public --The equipment and facilities used in the provision of pharmacy services safeguard the health, safety and wellbeing of patients and the public.			
5.2.1	External inspection process				
5.2.2	External inspection schedule				
5.3	Legal process for inspection	THE PHARMACY (PREMISES STANDARDS, INFORMATION OBLIGATIONS, ETC.) ORDER 2016			

5.4	Process for discrepancies	Use statutory enforcement powers in situations when a pharmacy owner does not complete an improvement action plan and carry out the necessary changes to make sure standards are met, or in situations when there is a serious risk to patient safety.			
21. Section	**Variable**	**Information**			
1	**Reference**		Sweden		
1.1	Publication I.D.	Läkemedelsverkets föreskrifter (LVFS 2010:4) om tillverkning av extemporeläkemedel1		Yes	Yes (in conjunction with EudraLex)
1.2	Date	2010			
2	**Country**	Sweden			
3	**Standard implemented**				
3.1	Type	Regulatory document			
3.2	Headings	GMP Quality assurance system Staff and organisation Training Premises and equipment Documentation and manufacturing Quality control Storage Complaints, deviating events and cancellations			
3.3	Reference protocol standards	EudraLex Volume 4			

3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	Sweden			
4.2	Author	Swedish Medical Products Agency			
4.3	Drafting role	Full			
4.4	Implementation role	Guidance not legally binding but provides examples and recommendations			
5	**Audit process**				
5.1	Internal inspection				
5.1.1	Internal inspection process	Self-inspection to ensure GMP is observed. Minutes of completed self-inspections and corrections made shall be kept and archived. Training or staff and records of such Pharmacist must complete check on production means and documents Regular check and test of aseptic technique			
5.1.2	Internal inspection schedule	"Regular", or at least once a year			
5.2	External inspection				

5.2.1	External inspection process	None mentioned, handled by Swedish medical products agency			
5.2.2	External inspection schedule				
5.3	Legal process for inspection	Swedish Board of Medicines' regulations (LVFS 2010: 12) on permits for extemporaneous pharmacies. (HSLF-FS 2016: 29)			
5.4	Process for discrepancies				
22. Section	**Variable**	**Information**	**International**	**No**	**Np**
1	**Reference**				
1.1	Publication I.D.	ISOPP safe handling of cytotoxic			
1.2	Date	2022			
2	**Country**	International			
3	**Standard implemented**				
3.1	Type	Guidelines			

3.2	Headings	Introduction Transport of cytotoxic drugs Personnel Education and training Hierarchic order in protection measures Facilities for sterile cytotoxic reconstitution and personal protective equipment Containment systems (including closed-system transfer devices (CSTDs) Containment primary engineering controls (C-PECs) Nonsterile preparations Cytotoxic drug contamination monitoring Checking procedures Safe administration of C617 C621cytotoxic drugs and monoclonal antibodies Cleaning procedures Cytotoxic spills, extravasation, and other incidents Waste handling and patient excreta Warning staff of the presence of cytotoxic drugs Home care Risk management Medicines management Documentation Monoclonal antibodies Automation Oral anticancer therapies Investigational drugs Medical surveillance Computerised prescribing, dispensing and administration Dose banding Safe handling of hazardous drugs in research facilities			

3.3	Reference protocol standards	Update on 2007 standards, 21 revised standards and 8 newly added			
3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	N/a			
4.2	Author	International Society of Oncology Pharmacy Practitioners			
4.3	Drafting role	Systematic and evidence review of old standards by ISOPP standards task force			
4.4	Implementation role	advocacy tool, defers to compliance with national/international used standards, hopes to add to safety			
5	**Audit process**				
5.1	Internal inspection				
5.1.1	Internal inspection process	Provides audit toolkit Education every 2/3 years Same environmental monitoring as PIC/S			
5.1.2	Internal inspection schedule				
5.2	External inspection	Handled by national authorities			

5.2.1	External inspection process				
5.2.2	External inspection schedule				
5.3	Legal process for inspection				
5.4	Process for discrepancies				
23.	**Variable**	**Information**	**Netherlands**	**Yes**	**Yes**
1	**Reference**				
1.1	Publication I.D.	GMP-Z			
1.2	Date	2011			
2	**Country**	Netherlands			
3	**Standard implemented**				
3.1	Type	Standard			
3.2	Headings	Pharmaceutical Quality System* Personnel Rooms and equipment* Documentation Production Quality Control Outsourced activities* Complaints, quality defects and recalls*			

		Self-inspection Assessment application and design quality of pharmacy compounding* Individual preparations Aseptic practices Handling with hazardous substances and preparations* GMP for ATMP			
3.3	Reference protocol standards	EU GMP			
3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	Netherlands			
4.2	Author	Dutch association of hospital pharmacists			
4.3	Drafting role	partnership of the Dutch association of hospital pharmacists, the health and youth inspectorate, universities and the The Royal Dutch Society for the Promotion of Pharmacy			
4.4	Implementation role	Guidelines, assessed by department with full responsibility for healthcare (Inspectorate)			
5	**Audit process**				
5.1	Internal inspection				

5.1.1	Internal inspection process	Self-inspection chapter mentions: Personnel matters, premises, equipment, documentation, production, quality control, distribution of the medicinal products, arrangements for dealing with complaints and recalls, and self-inspection, should be examined at intervals following a pre-arranged programme			
5.1.2	Internal inspection schedule	No specific mentioned, usual yearly and 6 monthly monitoring and training in EU GMP			
5.2	External inspection				
5.2.1	External inspection process	Inspected by Inspectorate for Healthcare and Youth			
5.2.2	External inspection schedule				
5.3	Legal process for inspection	[Health Care Professionals Act] Article 100 of medicines act			
5.4	Process for discrepancies	decide on a formal warning, an official reprimand, a fine or a temporary or permanent prohibition of pharmacy practice Based on regulation set out in Health care professionals act articles 65–74.			
24. Section	**Variable**	**Information**			
1	**Reference**			No	No
1.1	Publication I.D.	NIOSH Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings			

1.2	Date	2004			
2	**Country**	USA			
3	**Standard implemented**				
3.1	Type	Report with recommendations			
3.2	Headings	Receiving and Storage Drug Preparation and Administration Ventilated Cabinets Routine Cleaning, Decontaminating, Housekeeping, and Waste Disposal+C729 Spill Control Medical Surveillance			
3.3	Reference protocol standards				
3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	USA			
4.2	Author	National institute for occupational safety and health			
4.3	Drafting role	Full			
4.4	Implementation role	Recommendations only			
5	**Audit process**				

5.1	Internal inspection	No detailed audit process mentioned, other than "regular" assessment of procedures and inventory			
5.1.1	Internal inspection process				
5.1.2	Internal inspection schedule				
5.2	External inspection	None mentioned			
5.2.1	External inspection process				
5.2.2	External inspection schedule				
5.3	Legal process for inspection				
5.4	Process for discrepancies				
25. Section	**Variable**	**Information**	https://osha.europa.eu/en/legislation/directive/directive-200437ec-carcinogens-or-mutagens-work#:~:text=This%20Directive%20covers%20the%20protection,covered%20by%20the%20Euratom%20Treaty.	**No**	**EU directive**
1	**Reference**				

1.1	Publication I.D.	Directive 2004/37/EC - carcinogens, mutagens or reprotoxic substances at work			
1.2	Date	Last updated 2021			
2	**Country**	EU			
3	**Standard implemented**				
3.1	Type	Directive, must be transposed to member state law			
3.2	Headings	Risk assessment Prevention measures Training and information Consultation and participation of workers Health surveillance			
3.3	Reference protocol standards	n/a			
3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	EU			
4.2	Author	EC			
4.3	Drafting role				
4.4	Implementation role	None as of yet, plan to launch in 2022 the process to evaluate the implementation of the Directive			

5	**Audit process**	None mentioned			
5.1	Internal inspection				
5.1.1	Internal inspection process				
5.1.2	Internal inspection schedule				
5.2	External inspection				
5.2.1	External inspection process				
5.2.2	External inspection schedule				
5.3	Legal process for inspection				
5.4	Process for discrepancies				
26. Section	**Variable**	**Information**	**Germany**	**Yes**	**Guideline only**

1	**Reference**		Germany hospital pharmacies adhere to general state pharmacy operating regulations, the GMP regulations and special requirements for certification- Onkozert, performed on behalf of the German Cancer Society		
1.1	Publication I.D.	ADKA guideline: Aseptic production and Testing of ready-to-use parenterals			
1.2	Date	2012			
2	**Country**	Germany			
3	**Standard implemented**				
3.1	Type				
3.2	Headings	Purpose and scope Regulatory Requirements Responsibilities . Quality standard for the aseptic manufacture and testing of ready-to-use parenterals Premises Staff Sanitary measures Preparation Identification Examination Microbiological Validation and Monitoring of Aseptic Manufacturing documentation Storage/transportation			
3.3	Reference protocol standards	PIC/S USP 797 and EudraLex			

3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	Germany			
4.2	Author	German Society pf Hospital Pharmacists (ADKA)			
4.3	Drafting role				
4.4	Implementation role	Guideline only			
5	**Audit process**				
5.1	Internal inspection				
5.1.1	Internal inspection process	No audit process mentioned			
5.1.2	Internal inspection schedule	Annual internal audits Yearly training of staff Yearly filling test Yearly microbiological test			
5.2	External inspection				
5.2.1	External inspection process	German hospital pharmacies audited by regional supervisory authority and some external regions			

5.2.2	External inspection schedule	None mentioned			
5.3	Legal process for inspection	Ordinance on the operation of pharmacies (pharmacy operating regulations - ApBetrO)			
5.4	Process for discrepancies				
27. Section	**Variable**	**Information**	**Germany**		
1	**Reference**			No	Yes
1.1	Publication I.D.	Ordinance on the application of good manufacturing practice in the manufacture of medicinal products and active ingredients and on the application of good professional practice in the manufacture of products of human origin (AMHWV)			
1.2	Date	2012			
2	**Country**	Germany			
3	**Standard implemented**				
3.1	Type	Standard			

3.2	Headings	Relevant only: Quality Management System Good Manufacturing Practice and Good Professional Practice Personnel Operating rooms and equipment Hygiene measures Storage and Transport Animal husbandry Activities on behalf General Documentation Self-Inspections and Supplier Qualification			
3.3	Reference protocol standards				
3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	Germany			
4.2	Author	Federal Justice Ministry			
4.3	Drafting role	Full			
4.4	Implementation role	Inspection as set out in ApBetrO, regular pharmacy inspection process			
5	**Audit process**				
5.1	Internal inspection				

5.1.1	Internal inspection process	Should be set out in predetermined program Can be done by trained personnel on site or trained third independent party			
5.1.2	Internal inspection schedule	"Regular"			
5.2	External inspection				
5.2.1	External inspection process	German hospital pharmacies audited by regional supervisory authority and some external regions			
5.2.2	External inspection schedule				
5.3	Legal process for inspection	Ordinance on the operation of pharmacies (pharmacy operating regulations - ApBetrO)			
5.4	Process for discrepancies				
28. Section	**Variable**	**Information**	**Germany**	**Yes**	**Yes**
1	**Reference**		Germany hospital pharmacies adhere to general state pharmacy operating regulations, the GMP regulations and special requirements for certification- Onkozert, performed on behalf of the German Cancer Society		
1.1	Publication I.D.	TGA Good manufacturing practice for medicinal products			
1.2	Date	Updated 2022			

2	**Country**	Australia			
3	**Standard implemented**				
3.1	Type	Regulatory document			
3.2	Headings	Use same headings as PI(C/S			
3.3	Reference protocol standards	PIC/S GMP			
3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	Australia			
4.2	Author	Therapeutic Goods Administration			
4.3	Drafting role	Member of PIC/S, use recommendations from PIC/S			
4.4	Implementation role	See external inspection section			
5	**Audit process**				
5.1	Internal inspection				
5.1.1	Internal inspection process				

5.1.2	Internal inspection schedule				
5.2	External inspection				
5.2.1	External inspection process	Beginning meeting 1 to 5 working day inspection, audit of processes and documentation Letter drafted and reviewed by TGA before issue			
5.2.2	External inspection schedule	Risk based approach			
5.3	Legal process for inspection	Therapeutic goods act			
5.4	Process for discrepancies	Assigned: - critical (will result in regulatory action being considered, including suspension or cancellation of your GMP licence or GMP clearance) - major - other Can be updated if not addressed by follow up visit Given			
29. Section	**Variable**	**Information**		**Partial**	**Guideline**
1	**Reference**		Provide guidance to registered pharmacists in relation to the compounding (extemporaneous preparation) of medicines, not set out in legislation or a registration standard		

1.1	Publication I.D.	Pharmacy Board of Australia- Guidelines on Compounding Medicines			
1.2	Date	2012			
2	**Country**	Australia			
3	**Standard implemented**				
3.1	Type				
3.2	Headings	Instruction to compound a medicine Appropriate circumstances for compounding medicines Competence to undertake 'simple compounding' Competence to undertake 'complex compounding' Veterinary medicines Formulation considerations --RELEVANT SECTION---- Compounding of sterile injectable medicines----- RELEVANT SECTION --Compliance with legislation, guidelines and practice standards --Self-assessment and audit --Beyond use dates of compounded sterile injectable medicines Supervision of appropriately trained staff Facilities and equipment Managing risks that may lead to injury Raw Materials Quality Standards Reporting of adverse events Packaging and labelling requirements .Counselling and information for patients The patient's right to choose where to access all types of compounded medicines Advertising Reference texts and other sources of information relevant to compounding			

3.3	Reference protocol standards	PIC/S GMP, PIC/S medicinal products, USP 797			
3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	Australia			
4.2	Author	Pharmacy Board of Australia			
4.3	Drafting role	Utilised international standards, provides additional guidance			
4.4	Implementation role	No mention			
5	**Audit process**				
5.1	Internal inspection				
5.1.1	Internal inspection process	Should be Documented Adherence to standards measured Quality assurance plan and policy should be in place			
5.1.2	Internal inspection schedule	Not mentioned			
5.2	External inspection				

5.2.1	External inspection process	Not mentioned in standards Audit of past practice/CPD etc			
5.2.2	External inspection schedule	Random			
5.3	Legal process for inspection	Under section 41 of the National Law, these guidelines can be used in disciplinary proceedings under the National Law or law of a co-regulatory jurisdiction as evidence of what constitutes appropriate professional conduct or practice for pharmacists. When considering notifications (complaints) against pharmacists, the Board will give consideration to whether a breach of these guidelines has taken place			
5.4	Process for discrepancies				
30. Section	**Variable**	**Information**	These are standards of professional practice and not standards prepared or endorsed by the Standards Association of Australia. They are not legally binding	**Yes**	**No**
1	**Reference**		SHPA endorses PIC/S, these guidelines must be read in conjunction with PIC/S, provide instruction for PIC/S implementation		
1.1	Publication I.D.	SHPA Guidelines for Medicines prepared in Hospital Pharmacy Departments 2010			
1.2	Date	2010			
2	**Country**	Australia			
3	**Standard implemented**				

3.1	Type	Guideline			
3.2	Headings	SAME AS PIC/S guide Quality assurance system Personnel PREMISES AND EQUIPMENT Documentation QUALITY CONTROL Production WORK CONTRACTED OUT COMPLAINTS AND PRODUCT RECALLS SELF AUDITS			
3.3	Reference protocol standards				
3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	Australia			
4.2	Report to	The Society of Hospital Pharmacists of Australia Committee of Specialty Practice in Oncology			
4.3	Governing structure				
4.4	Drafting role	Full			
4.5	Implementation role	Guidance only, offer minimum standards for institutions			
5	**Audit process**				

5.1	Internal inspection				
5.1.1	Internal inspection process	program for continuing validation of aseptic technique and continuing validation in the preparation of all cytotoxic drug products must be implemented and documented. The quality assurance system, including personnel matters, premises, equipment, documentation, production, quality control, distribution of the medicinal products, arrangements for dealing with complaints and work contracted out			
5.1.2	Internal inspection schedule	Annual self-audit plan "Regular" audit activity			
5.2	External inspection	No role			
5.2.1	External inspection process				
5.2.2	External inspection schedule				
5.3	Legal process for inspection				
5.4	Process for discrepancies				
31. Section	**Variable**	**Information**		**Yes**	**No**

1	**Reference**		These are standards of professional practice and not standards prepared or endorsed by the Standards Association of Australia. They are not legally binding		
1.1	Publication I.D.	SHPA Standards of Practice for the Safe Handling of Cytotoxic Drugs in Pharmacy Departments			
1.2	Date	2010			
2	**Country**	Australia			
3	**Standard implemented**				
3.1	Type	Guideline			
3.2	Headings	**Introduction** **Objectives** **THE EXTENT AND OPERATION OF THE PRACTICE** **Policies and procedures** Cytotoxic Cabinets Cytotoxic cleanrooms Drug storage Protective clothing Preparation Waste management Cytotoxic Drug Spills Transport **RESOURCES** **STAFFING AND STRUCTURE LEVELS** Personnel considerations Personnel safety monitoring T**RAINING AND EDUCATION OF STAFF** **Quality** Monitoring **Documentation**			

3.3	Reference protocol standards				
3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	Australia			
4.2	Author	The Society of Hospital Pharmacists of Australia Committee of Specialty Practice in Oncology			
4.3	Drafting role	Full			
4.4	Implementation role	Guidance only, offer minimum standards for institutions			
5	**Audit process**				
5.1	Internal inspection				
5.1.1	Internal inspection process	program for continuing validation of aseptic technique and continuing validation in the preparation of all cytotoxic drug products must be implemented and documented.			
5.1.2	Internal inspection schedule				
5.2	External inspection	No role			

5.2.1	External inspection process				
5.2.2	External inspection schedule				
5.3	Legal process for inspection				
5.4	Process for discrepancies				
32. Section	**Variable**	**Information**	**All round pharmacy practice standard**	**Partial**	**Yes**
1	**Reference**		If conflict arises between the legislation and these standards, legislative requirements must be adhered to		
1.1	Publication I.D.	PSA Professional Practice standards			
1.2	Date	2017			
2	**Country**	Australia			
3	**Standard implemented**				
3.1	Type	Standard			
3.2	Headings	Relevant only Compounding --Quality assurance			

		--Policy and procedures --Training and education --Risk management and evaluation --Documentation --Facilities and equipment --Storage, stability, and disposal --Dispensing and other supply arrangements --Compounding practice --Counselling --Monitoring, review and follow-up			
3.3	Reference protocol standards				
3.4	Reference source (if applicable)				
4	**Responsible authority**				
4.1	Region of authority	Australia			
4.2	Author	Pharmaceutical Society of Australia			
4.3	Drafting role	Full			
4.4	Implementation role	Standard to be followed and endorsed by Pharmacy board in their inspections			
5	**Audit process**				
5.1	Internal inspection	No specific mention			

5.1.1	Internal inspection process				
5.1.2	Internal inspection schedule	Annual internal audits			
5.2	External inspection	No specific mention, handled by Pharmacy board			
5.2.1	External inspection process				
5.2.2	External inspection schedule				
5.3	Legal process for inspection				
5.4	Process for discrepancies				
Section. 33	**Variable**	**Information**			
1	Reference				
1.1	Publication I.D.	QuapoS 6 - Quality Standard for the Oncology Pharmacy Service			
1.2	Date	2018			
2	Country	Multinational			

3	Standard implemented				
3.1	Type	Guidelines			
3.2	Headings	Quality assurance Personnel Pharmacy anticancer drug unit Anticancer drug production Pharmacy as a co-ordination centre Pharmaceutical care			
3.3	Reference protocol standards	N/a			
3.4	Reference source (if applicable)	N/a			
4	Responsible authority				
4.1	Region of authority	Europe			
4.2	Author	European Society of Oncology Pharmacy			
4.3	Drafting role	Developed by the German Society for Onology Pharmacy (DGOP) in collabration with ESOP			
4.4	Implementation role	Standards for DGOP certification in Germany since 2001. Guidelines only outside fo Germany			
5	Audit process				
5.1	Internal inspection				

5.1.1	Internal inspection process	The clean room and equipment control require an ongoing monitoring program with appropriate intervals. For a controlled workplace and equipment the parameters to be checked include: QuapoS 620 ● microbiological contamination and active air samples; ● particulate counts; ● HEPA/ULPA filtration and integrity; ● room air quality and air changes per hour; ● velocity and pressure differentials. Surface monitoring: monitor production and administration areas in defined time intervals for various reasons such as evaluation of potential dermal exposure and health risks. Wipe sampling for surface residue of anticancer and other hazardous drugs in healthcare settings is currently the method of choice to determine surface contamination. Particle monitoring: A validated process must be in place for monitoring particles in the production area. Clean rooms should be routinely monitored based on a formal risk analysis and the results obtained during the classification of rooms. Production: Production is based on working rules for hazardous substances and the production specifications including the results of the hazard evaluation. The work techniques defined in the local regulations and production specifica- tions are mandatory. Compliance must be regularly inspected. Production Instructions: Production instructions are created and available before the start of any production process. Internal quality management assures standardised, general, active-substance-based or medicinal-product-based production. They should undergo regular review and updating within the scope of the QMS			
5.1.2	Internal inspection schedule	See above			
5.2	External inspection				

5.2.1	External inspection process	None mentioned			
5.2.2	External inspection schedule	None mentioned			
5.3	Legal process for inspection	None mentioned			
5.4	Process for discrepancies	None mentioned			
34.1.	Reference				
1.1	ID	Economic and Microbiologic Evaluation of Single-Dose Vial Extension for Hazardous Drugs.	USP 797 has since updated BUD in Class 5 or better to 12 hours!!!!!!!!!		
1.2	Author	Rowe, Erinn C.; Savage, Scott W.; Rutala, William A.; Weber, David J.; Gergen-Teague, Maria; Eckel, Stephen F.			
1.3	Year	2012			
2	QA standard referenced				
2.1	Reference	USP 797			
2.2	Region of origin	USA			
2.3	Type	Directive, adherence depends on state regulations			
3	Intervention				

3.1	Description	USP 797 dictates discarding when more than a 0.5-log10 unit increase in microbe growth compared with the previously measured value University of North Carolina (UNC) Hospitals and Clinics, approximately 125 hazardous CSPs are prepared daily, which is associated with a $20 million annual expense.			
3.2	Measurables	Cost of medicine discarded after 6 hours Savings if limit expanded to 24, 36, 48, 72 hours Microbiological growth after 24, 48, 72 hours, 7 and 14 days			
4	Comparator	n/a			
5	Outcome				
5.1	Measurables	Cost of discarding after 6 hours $766,709 annually annualized savings at each of these time points 3.8%, 4.5%, 4.7%, and 5.3% 101 drugs tested, 606 samples- Failures : 6H -2 24 - 2 48 - 1 72 - 3 7 days - 2 14 days-1 Provide an annual cost savings of more than $600,000			
5.2	QA tool benefits				
5.3	QA tool weaknesses	Guideline based on standard growth curve - whether systems or different conditions can prevent microbiologic contamination or if all medications allow this standard growth has not been evaluated No studies to document adverse effect of extended BUD Severe cost and waste implications			