



BEAM Pediatric Hospital Pharmacy

Den Haag

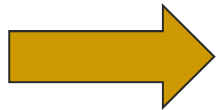
Group C

[Group C:]

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- Gudrun Sailer, Austria
- Laszlo Horvath, Hungary
- Evelyn Garvey, Ireland
- Helge Ovesen, Norway
- Giuseppe Caravella, Italy
- Per Nydert, Sweden

[BEAM Hospital]

- Pediatric Hospital
- 300 beds
- Intensive care
- General care



Small scale compounding unit

[Mission

- Ensure the quality and safety of pediatric oral drugs

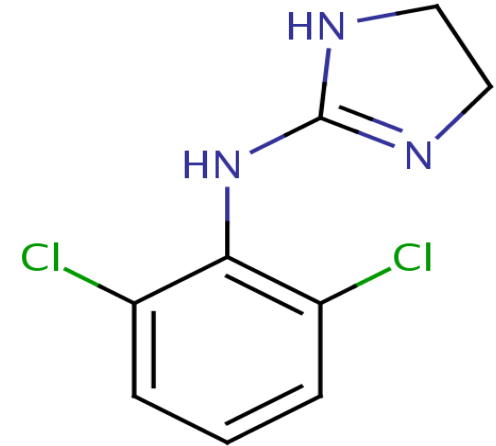
[Strategy]

- Production of oral medicinal products, ready to use
- in Individual doses
- cheaper than the industry
- safer than the alternative
- Provide knowledge and training to nursing staff

Our definition of small scale production

- Non-sterile
- Oral formulations
- No cytotoxics
- Individual dispensing
- Immediate use

[Clonidine Solution



- Solubility in water: 4.80e-01 mg/mL
- Bioavailability (Children): 55 %
- Route of administration: Oral
- Therapeutic category: alpha-2 agonist
- Indication (off label): premedication, pain control
- Dose interval: 3-12 microg/kg/day / 3-4times

[Other excipients]

- Sterile water (from bulk)
- pH adjustment with sodiumhydroxid (up to 6-7)
- Preserved with Methyl Parabene 0,1 %
- Taste: Raspberry

[Packaging material/design]

- Type II glass bottles for oral solution
- Oral syringes with cap for dispensing (immediate use < 24h)
- Labels for syringes designed after “Design for patient safety”

[Shelf life]

- 90 % after 8 months (literature review)
- → 6 months for our product

- Batch size:
 - 18 x 500ml bottles 5 microg/ml prn
 - 18 x 500ml bottles 20 microg/ml prn

[Analytical Quality Control]

- Audit supplier (GxP, ISO 15189)
- Identification of raw material (inhouse)
- Certificate of Analysis (raw material and packaging) from supplier
- Analytical testing final product (inhouse)
- Non sterile testing of oral products (Ph.Eur) – outsourced

[Business Plan]

- Current situation
 - Prepared on the ward.
 - Proposal to prepare in pharmacy in new compounding facility (see facility plan)
- Resources needed in pharmacy
 - Preparation time and dispensing time
 - Quality assurance
 - Prescriptions are checked by pharmacist before they are sent to compounding unit – not part of business plan
- Trends in therapies/future demands
 - Ability/facilities to prepare all oral dosage forms used at the wards

Risk assessment – move to pharmacy

	Severity	Detection	Probability	Score
Dilute at ward	2	2	2	8
Dilute at pharmacy	2	1	1	2
IV use of oral drug (ward)	2	3	2	12
IV use of oral drug (pharmacy)	2	1	1	2

[Business Plan II

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- Equipment
 - Ventilation
 - Construction
 - compounding room grade D
 - dispensing room grade D
 - Water supply
 - Tap water for cleaning
 - (will use purified water for rinsing from industry)
 - All materials are disposable
 - Weighing balance
 - Pumps (Baxa 2011) to fill syringes with label
 - Rapid fill 2011- can interface with computer system – automatically prepare required dose
 - Computers, label printers



[Business Plan III]

- Personnel
 - See org chart
 - Training and competency assessment (1 week)
 - Being open policy
- Quality Management System
 - See later slide

[Business Plan V]

- Logistics
 - Storage facility (see plan)
 - Procurement (pharmacy technician)
 - Tube post
- Costs/Financing
 - Investment: building cost, validation and training
 - Price model: drug cost + fixed addition inc margin
 - Return on investment is positive
 - Yearly review of pricing related to doses dispensed
 - Consider dosebanding in the future

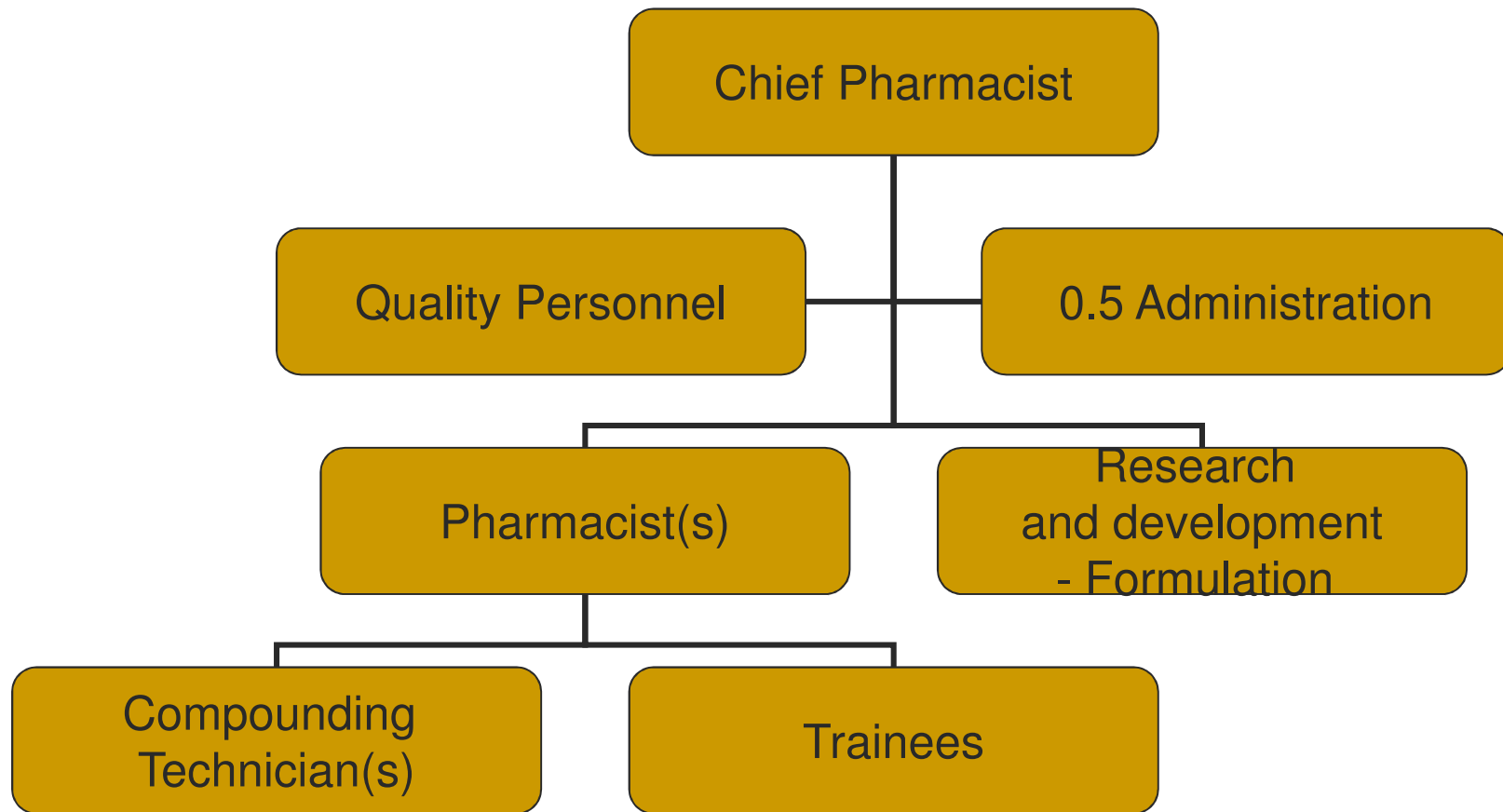
[Business Plan VI]

- SLA with hospital wards
 - Delivery within 2 hours
 - Possibility for stat orders (15 min)
 - Opening hours: 24/7

[Site Master File]

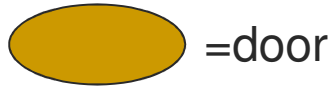
- General information (already presented)
- Personnel
- Premises and equipment
- Quality Control

Compounding Pharmacy Organisation Chart



[Quality Control]

- Electronic documentation connected to CPOE
- Internal audit every year
- Product recall
- Written instructions (SOP)
- Change control
- Database for reporting deviations, medication errors, ADE report system
- → check list for handling complaints from customer



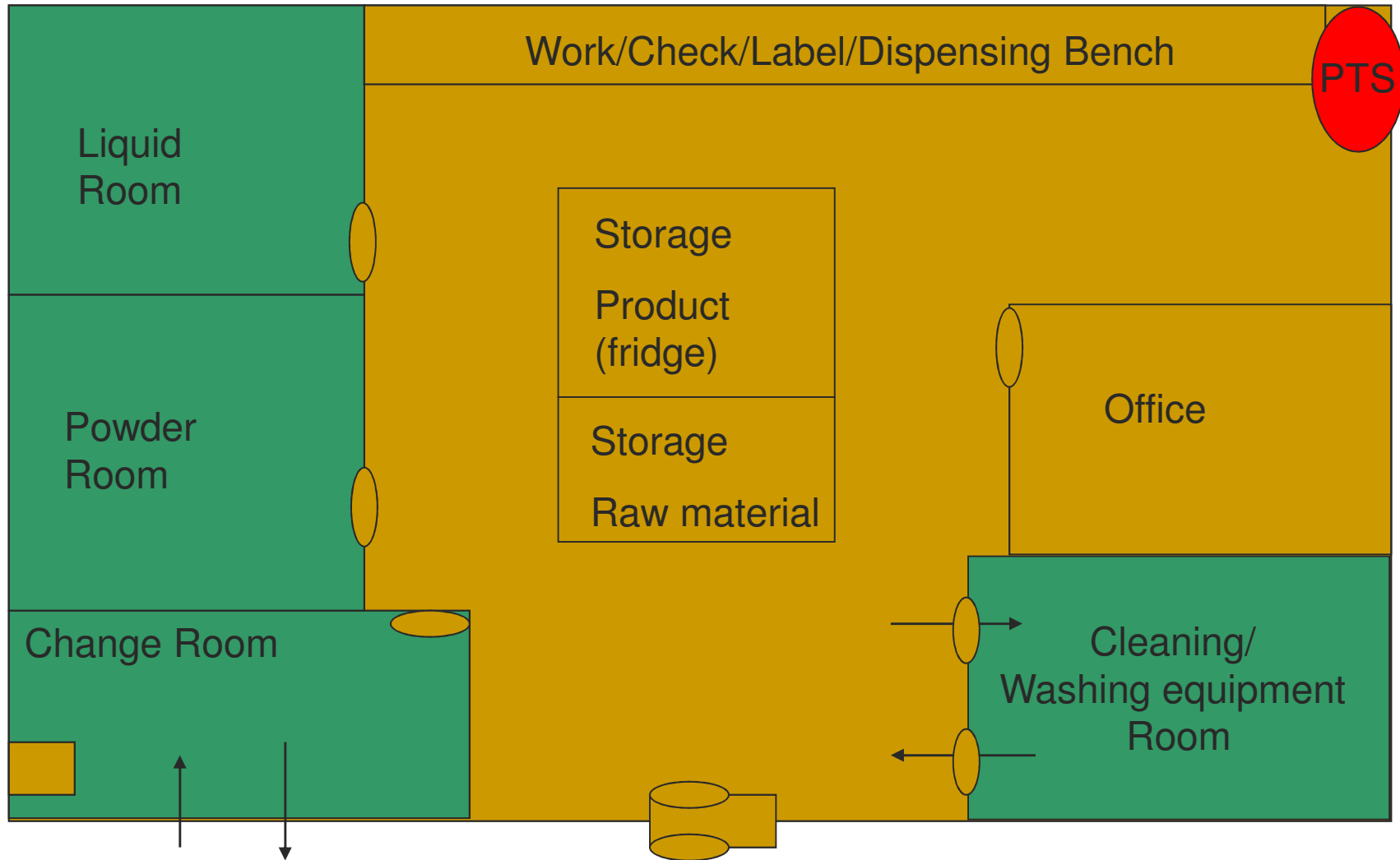
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Preparation Facilities

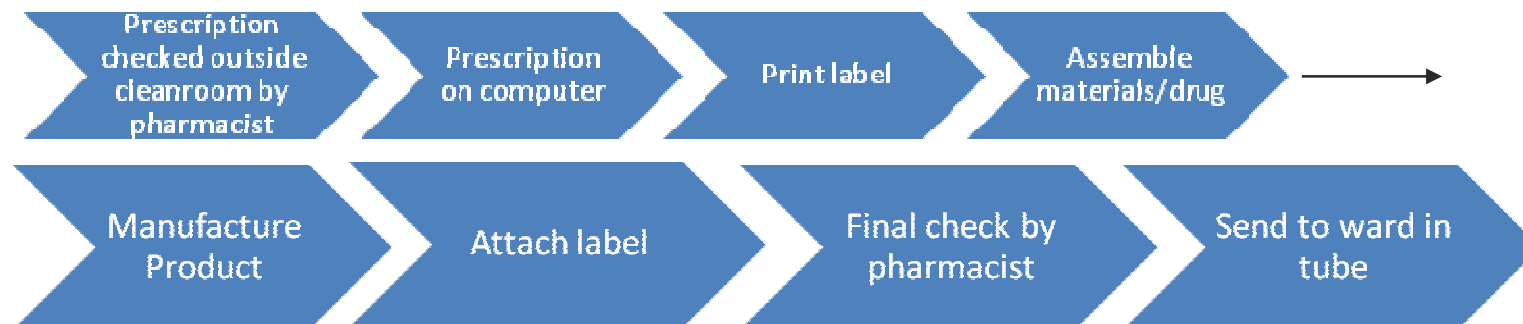


[Production Process]

■ Preparation of bulk solution



■ Dispensing of syringes



[Validation Master Plan]

- Validation is planned
 - DQ
 - IQ
 - OQ
 - PQ
- Validation Summary Report

Validation Objects

Objects:	DQ	IQ	OQ	PQ
Rooms HVAC	x	x	X	x
Scales Pumps	X	X	X	
Personnel	-	-	-	
Cleaning Validation	Separate VMP			
Computer Validation	Separate VMP			

[Revalidation program]

- Monitoring particle level
- Monitoring microbiology
- Retraining of staff
- Change control system

[Service Level Agreement]

- Technical department
- IT
- Analytical lab
- Microbiology
- Cleaning services



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