



Donor recruitment, assessment, and screening

Susan Mikkelsen, specialist physician, Department of Clinical Immunology, Aarhus University Hospital

Agenda



- Introduction to the Department of Clinical Immunology
 - Current authorisations: tissues and cells, blood and plasma, and organs.
 - **The quality management system**
 - **Traceability, coding and IT systems**
 - **Vigilance and reporting**
- Implementing faeces donor recruitment, faeces donor screening, and faeces processing in the blood centre facilities.
 - **Donor recruitment, registration, history review and medical examination**
 - **Donor protection. Voluntary and unpaid donation**
 - **Questionnaire, blood, and faeces screening**
 - **Donor approval**
 - Supply continuity

Some of the illustrations in the slideshow are in Danish. They are screenshots from our systems.



Department of Clinical Immunology



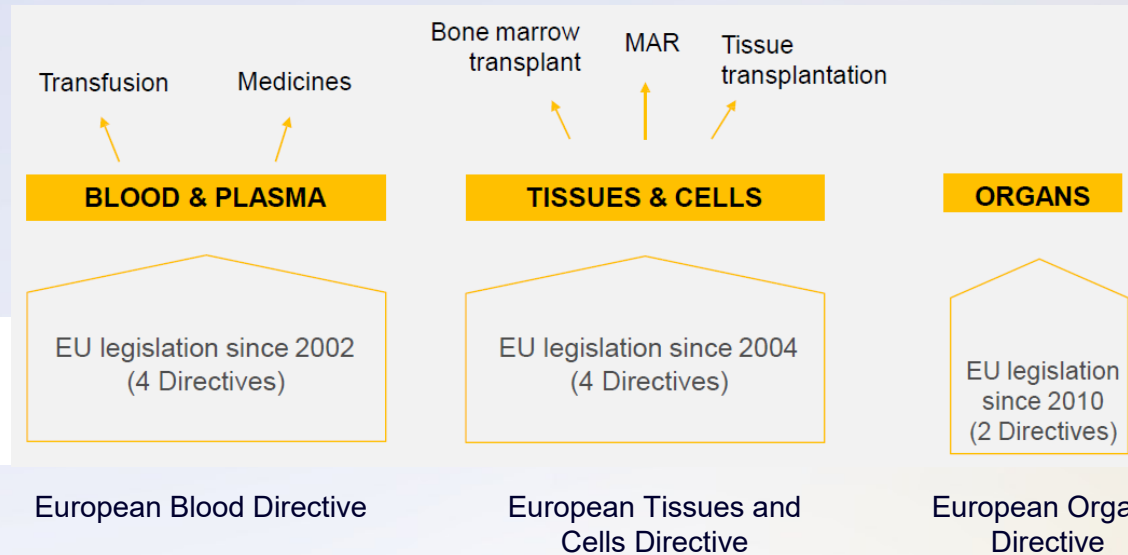
The Department of Clinical Immunology specializes in:

- diseases of the immune system
- transplantation immunology
- transfusion medicine
- blood banking

Department of Clinical Immunology



Current EU SoHO legislation on safety and quality



National competent authorities are responsible for the implementation of EU legislation



The image shows two authorization certificates from the Danish Patient Safety Authority (DANSK PATIENTSikkerhed). Both certificates are issued to Aarhus University Hospital (Aarhus Universitetshospital) for the handling of human tissues and cells.

Top Certificate: Tilladelse til blodcentervirksomhed
 This certificate authorizes the handling of blood. The authorized establishment is Blodcenter Midt, located at Blodbank & Immunologi, Aarhus Universitetshospital, Palle Juul-Jensens Boulevard 99, 8200 Aarhus N. The certificate number is Sagsnr. 35-3512-39, dated 9/5-25.

Bottom Certificate: Tilladelse til vævscenter til håndtering af humane væv og celler
 This certificate authorizes the handling of human tissues and cells. The authorized establishment is Blodbank & Immunologi, vævscenter, located at Aarhus Universitetshospital, Palle Juul-Jensens Boulevard 99, DK-8200 Aarhus N.



Department of Clinical Immunology

Legislations and standards

Several national regulations



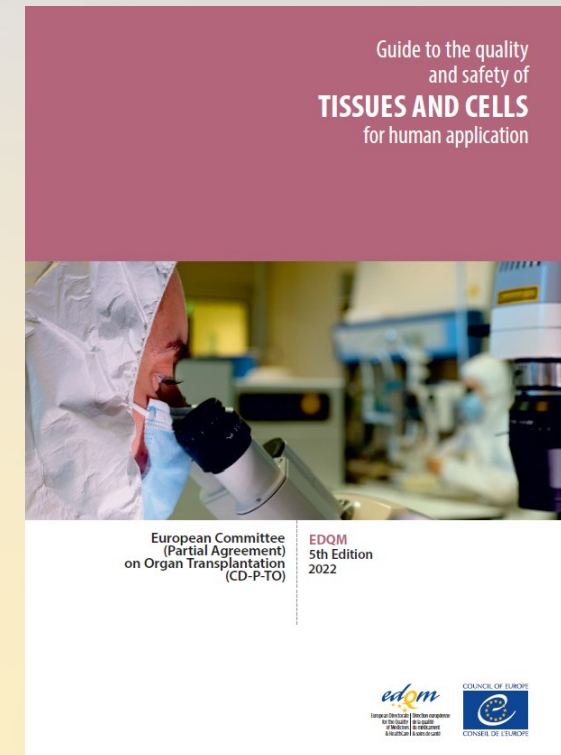
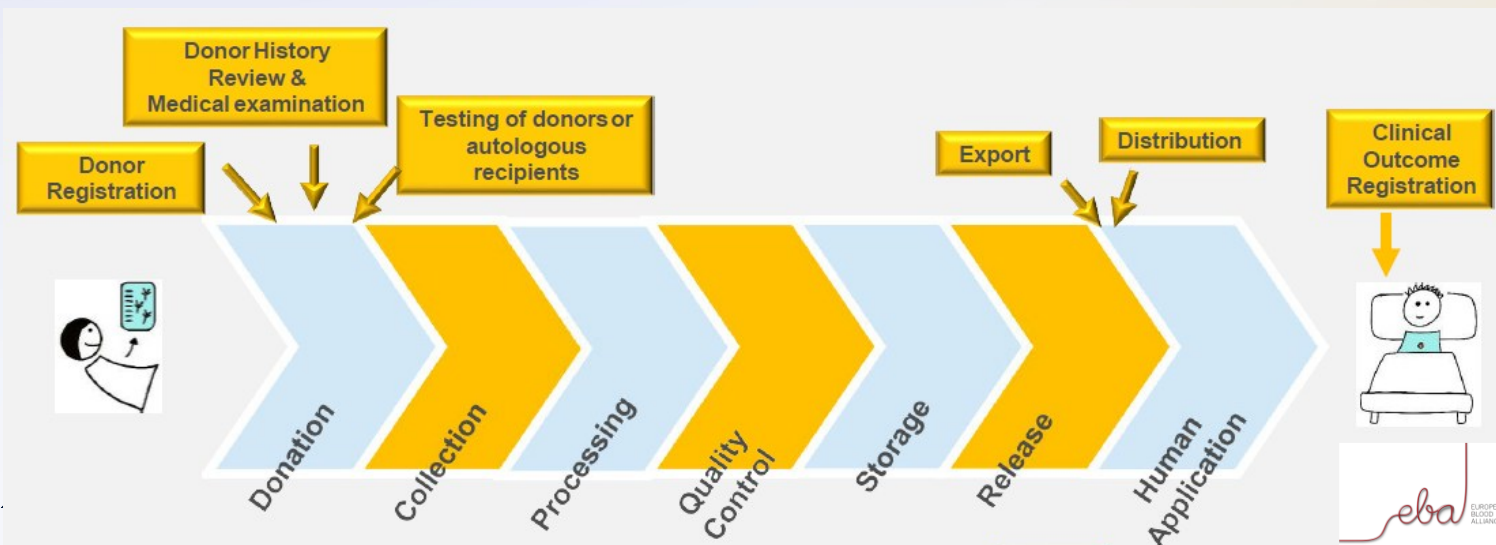


Quality Management System (QMS)

A formalised system that documents processes, procedures, and responsibilities

Why do we need a QMS?

- To support achieving defined quality standards in a consistent manner
- To focus on risks and opportunities for improvement
- To obtain and maintain authority license and accreditations





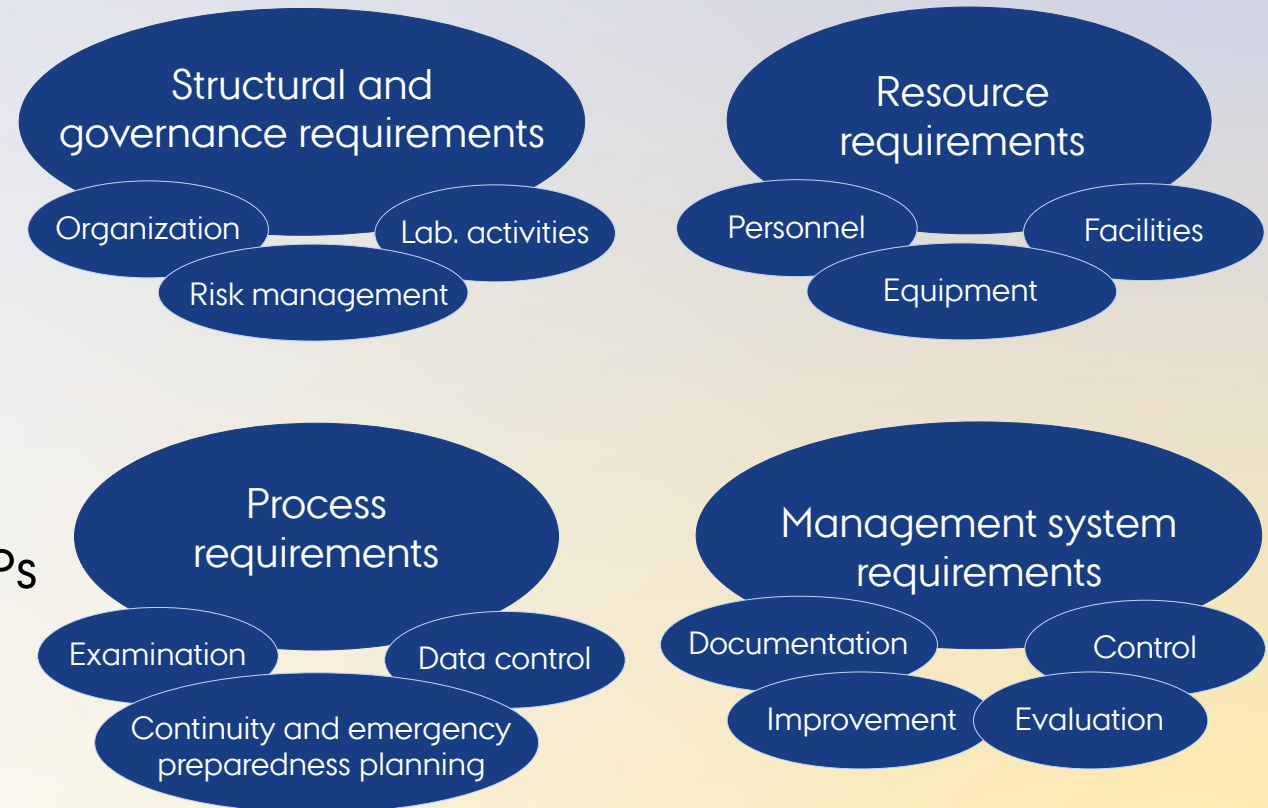
Quality Management System (QMS)

Key elements

The **quality manual** describes the quality management system of the organisation.

The quality manual

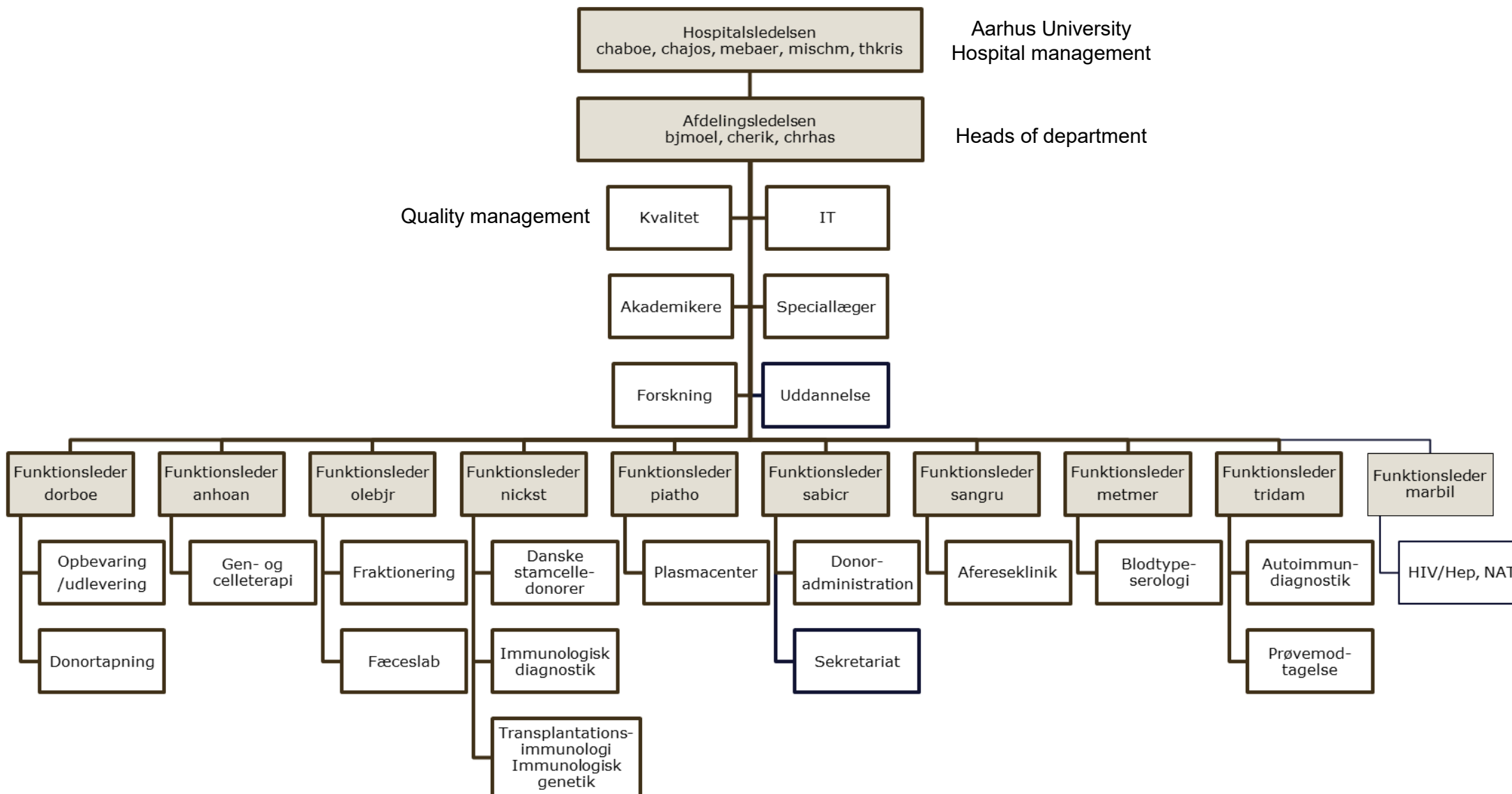
- clearly communicate information
- serve as a framework for meeting quality system requirements
- describe how all the related quality processes occur with references to the SOPs





Organization

Documentation of roles, responsibilities of personnel and organization.



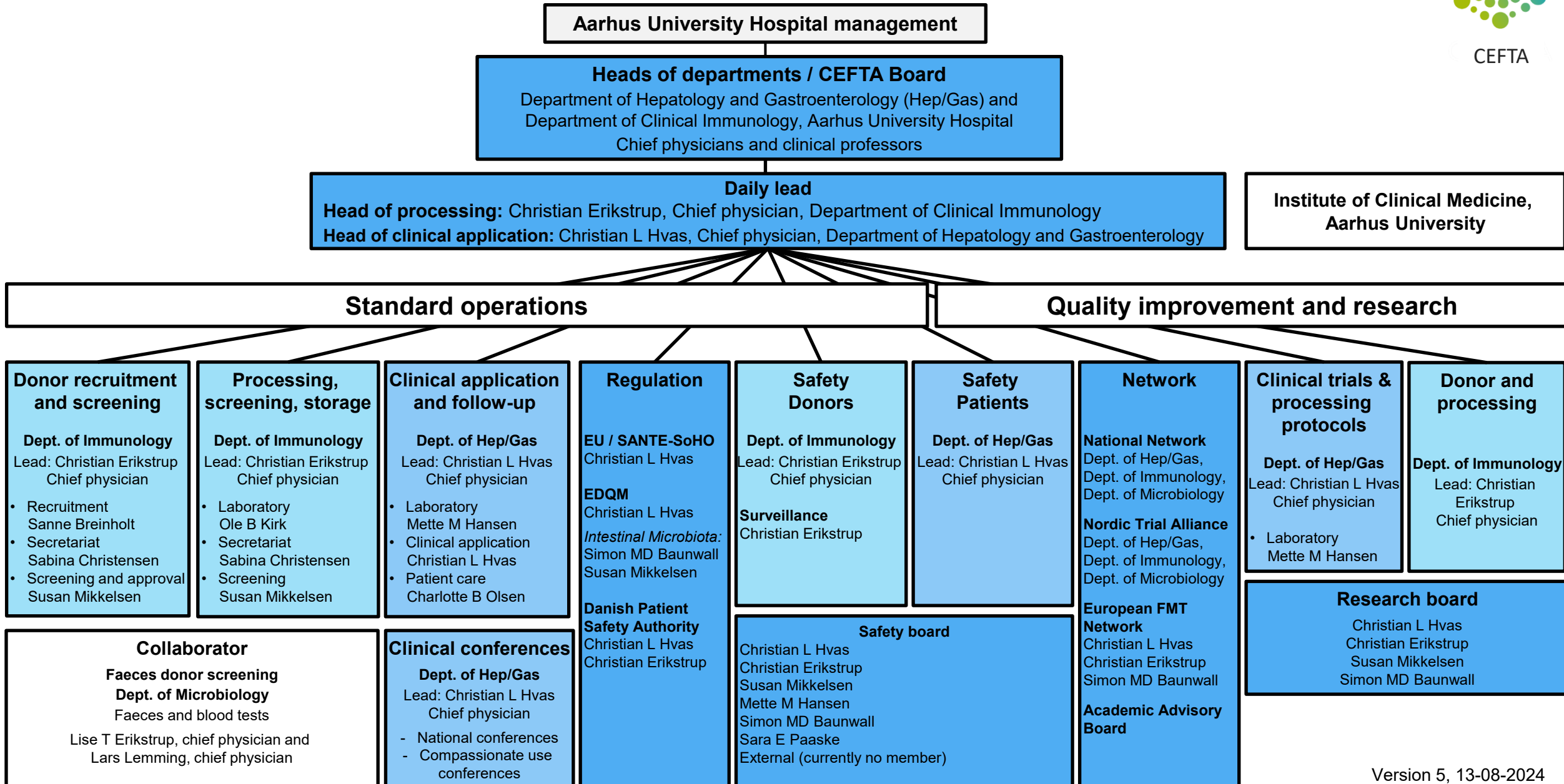


Responsibilities

Juridisk/akkrediteringsansvar	BJMOEL	CHERIK	JEMJEN	PERKOE	RANBER	STIWIL	TRIKOR
§§ 4- og 5-ansvarlig, Vævsloven	x						
§ 6-ansvarlig, Blodforsyningsloven	x						
§ 39-ansvarlig, GMP	x						
Responsible Person	x						
Qualified Person						x	
Director, EFI	x						
Co-Director, EFI				x	x		
Laboratorieforsker, ISO 15189	x						
Bemyndiget person, DANAK	x	x	x	x			x
Director, JACIE (jf. funktionsbeskrivelse)	x				x		
Sikrings- og strålingsansvarlig, SST				x			
WMDA CEO				x			
WMDA Medical Director					x		

Kvalitet	ANRJR	ANTCRI	HEITOB	HELEBO	KIBUND	KISPEE	LAUSKE	LISEBI	LOUTIL	MICHIS	PIMUNK	STIWIL
Kvalitetsansvarlig farmaceut												x
Kvalitetsansvarlig bioanalytiker		x										
Kvalitetskoordinator						x						
GMP-frigivelse, Plasma		x				x						x
GMP-frigivelse, Plasma kvartalsopgørelse		x										x
GMP-frigivelse, ATMP												x
Superbruger, StruxureWare	x	x			x					x		
e-Dok Dokumentkoordinator		x	x			x	x					x
Stikprøvekvalitetskontrol	x	x		x		x			x			
Auditor		x				x		x			x	x

Fæceslaboratorie	CHERIK	LNILSE	OLEBJR	SANSCH	SUSAH1
Overbioanalytiker			x		
Teamleder	x		x		
Ansvarlig læge	x				
Afdelingslæge					x
Specialist		x		x	



Quality Management System (QMS)



Personnel

Trained personnel with documented and periodically assessed competence to perform the tasks allocated to them.

- Trained personnel with documented and periodically assessed competence to perform the tasks allocated to them.
- Program for introduction, training and re-training, monitoring of competences and authorization to perform each function.
- Personnel records
- Job descriptions should reflect all skills needed and accurately describe tasks, roles, and authorities.

Quality Management System (QMS)



Risk management

Identify risks and opportunities for improvement. Develop, document, and implement any necessary actions.

- Systematic process to identify and control potential quality issues.
- Risk review is ongoing as a part of deviations, validations, audit, and change control.
- Tools to identify, analyze and evaluate risk can be useful
- Risk evaluation:
 - what might go wrong?
 - what is the probability?
 - what is the consequences?

Quality Management System (QMS)



Facilities

Suitable for the activities and designed and maintained in a manner that prevent contamination and loss of traceability.

- Suitable for the activities and designed and maintained in a manner that prevent contamination and loss of traceability.
- A plan for access, cleaning, maintenance and quality monitoring
- Emergency plans
- Disposal of waste

Faciliteter og rengøringsfrekvens			
Udgiver	Blod- og Vævscenter Midt - Faglig > Kvalitet og Data		
Fagligt ansvarlig	Kirstine Marie Flæng Pedersen	Version	2
Kvalitetsansvarlig	Annette Heegaard Christensen	Gældende fra	11-01-2025
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Ændringer	Skema "Faciliteter": Køle-Fryserum - Nej" - indsat " henviser til "Udstyrskontrol"		

Dette supplerende dokument knytter sig til: [Faciliteter og miljøforhold](#).

Supplerende

Generelt

Der er forskellige krav til, hvor rene faciliteter skal være, idet det afhænger af aktiviteterne i de pågældende faciliteter. For at sikre, at rengøringen er tilpasset aktiviteterne, er der fastsat en række krav til rengøringen.

Rengøring af faciliteter foretages jf. den nationale retningslinje [Statens Seruminstitut, NIR for rengøring i hospitals- og primærsektoren, 2.1 udgave 2023](#), hvori hygiejne- og kvalitetsprofiler er fastsat - se Definitioner. I faciliteter, hvori der produceres og opbevares plasma til fraktionering og ATMP er der desuden fastsat krav i GMP-reglerne. For visse faciliteter skal udført rengøring dokumenteres. Nedenfor er krav til dokumentation angivet.

Rengøringen er på visse adresser uddelegeret til samarbejdspartnere, og der forefindes aftaler, rengøringplaner eller lignende, hvori krav til rengøring, rengøringsfrekvens og oplæring, træning og kompetence af personale, der varetager rengøringen, er beskrevet.

Opbevaringsfaciliteter skal overvåges for skadedyr, og kontrol heraf dokumenteres. Derudover er der indgået aftaler med skadedyrsbekæmpelsesfirmaer, og de ansvarlige i afdelingerne får en rapport fra disse kontrolbesøg, og ved fund af skadedyr iværksættes en korrigerende handling - evt. i samarbejde med skadedyrsbekæmpelsesfirmaet.

Der henvises til [Faciliteter og miljøforhold](#) samt [Anvendelsesområde](#).

Definitioner

Tabel 4 side 18 i NIR (se [Reference](#))

Hygiejneprofil 5 Kvalitetsprofil 5	Hygiejneprofil 4 Kvalitetsprofil 4	Hygiejneprofil 3 Kvalitetsprofil 3
<ul style="list-style-type: none">• Højlagre*• Operationstue	<ul style="list-style-type: none">• Bad og/eller toilet, puslerum	<ul style="list-style-type: none">• Gang på kliniske afsnit• Kapel, 6 timerstue og

Quality Management System (QMS)



Equipment

Processes for selection, testing, validation, qualification, use, and maintenance of equipment. This includes hardware, software and information systems. Examining laboratory performance and comparing it to e.g., standards.

- Description
- Manual for operating
- Procedures for testing and approval before use
- Procedure for service, control and maintenance
- Back-up
- Log-book

Valideringsprotokol - Laboratoricentrifuger

Baggrund	<p><i>Kort beskrivelse af centrifugen og dets tilsigtede anvendelse.</i></p> <p><i>Hvad er formålet med valideringen f.eks. nyt udstyr</i></p> <p><i>Beskrivelse af specifikationer - hvis ikke beskrevet under Laboratorieudstørsbeskrivelse</i></p>
Anvendelses-område	<p><i>Hvor (område/lokaltitet) skal det validerede anvendes</i></p>
Acceptkriterier	<ul style="list-style-type: none"> • Centrifugen skal opfylde krav mht. det lovpligtige centrifuge-eftersyn, herunder <ul style="list-style-type: none"> - udføre automatisk stop ved ubalance (slingrekontakt) - vise at den programmerede hastighed (RPM) er overensstemmende med henholdsvis den viste og den målte hastighed - sikre at højest tilladelige omdrejningstal (RPM) for centrifugen ikke overskrides • Den programmerede centrifugeringstid skal være overensstemmende med den målte tid med max 5% afvigelse. • Ved anvendelse af kølefunktion skal den programmerede temperatur sikre, at temperaturpåvirkning under centrifugeringen overholder de fastlagte temperaturkrav, der er opsat for prøvematerialet - f. eks +4 til +25° C. for blodprøver til blodtypeserologiske analyser • For analyser med fastsat G-værdi ved centrifugering, skal afpipettering og prøvematerialet på automatisk analyseudstyr kunne generere analyseresultater, der opfylder kriterier for den specifikke analyse.
Referencer	<ul style="list-style-type: none"> • Laboratoricentrifuger skal opfylde gældende bekendtgørelse for centrifuger BEK nr. 776 af 25. november 1991. • Centrifugen skal være CE-mærket med fabrikantens/importørens navn og adresse, fabrikationsår, nummer og max omdrejningstal. CE-mærkning er en nøgleindikator for et produkts overholdelse af EU-lovgivningen og muliggør varenes fri bevægelighed på det europæiske marked.
Funktionelle specifikationer	<p>Laboratoricentrifuger udgør en mekanisk fare pga deres høje hastighed, og skal derfor være udstyret med en række sikkerhedsanordninger:</p>

Quality Management System (QMS)



Critical materials (purchasing and inventory)

Process for selection, procurement, reception, storage, acceptance testing of raw materials and supplies.
A good inventory management system ensures uninterrupted service as supplies are available when required.

- All materials must be tested, clearly identified and traceable
- Control during all steps

Kvalitetsledelsessystemet

Bestilling og modtagelse af varer fra ekstern leverandør, version 6

Blod-/Vævscenter



BESTILLING

Ekstern leverandør (se evt. ordreliste):

Varenavn (se evt. ordreliste):

Antal (se evt. ordreliste):

Ordreliste vedhæftet

Dato/regions-ID:

VISUEL VURDERING - MODTAGELSE

Følgeseddel vedhæftet (Lot-nr. fremgår af følgeseddel)

Lot-nr.:

Stuetemperatur

Køl kl.:

Frys kl.:

karantænelager (karantæne etiket påsat)

Udløbsdato:

Fremgår af følgeseddel

Styres via elektronisk system, lagerstyring, kalender e. lign.

Dato/regions-ID:

VISUEL KONTROL OG KVALIFICERING

Visuel kontrol udført

Visuel kontrol udføres før ibrugtagning

Kvalificering:

Serologisk, genomisk, anden (dokumentation og evt. frigivelse på kvalificeringsdokumentet)

Release Certificate (vedhæftet/gemt elektronisk)

Reagens Insert (vedhæftet/gemt elektronisk)

Dato/regions-ID:

Quality Management System (QMS)



Process control

Ensuring the quality of the laboratory testing processes: quality control, monitoring of key performance indicators, and verification and validation of methods.

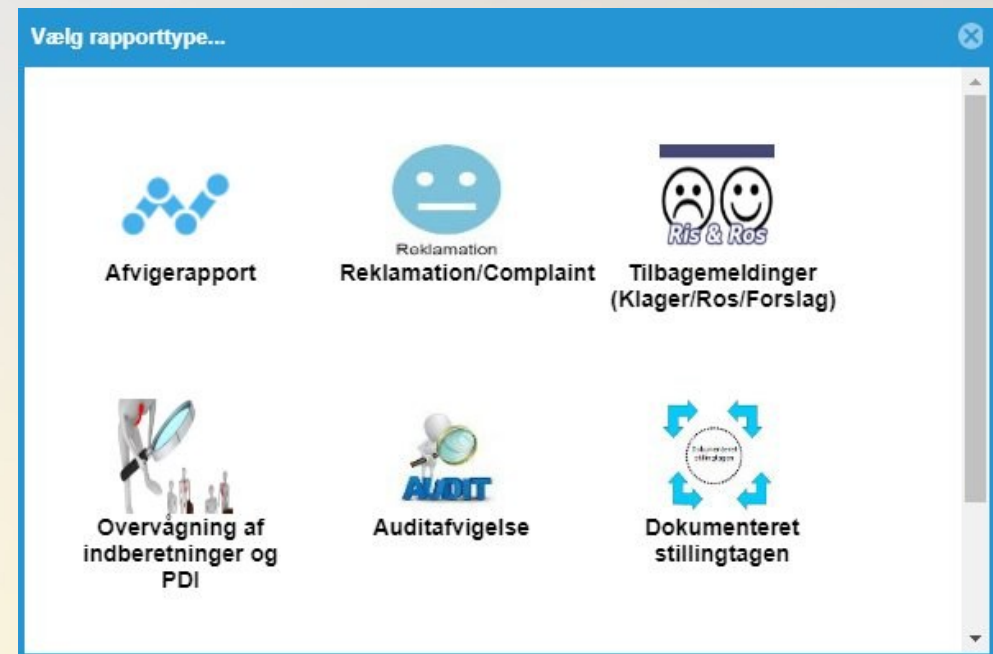
All processes are described in SOPs

Quality Management System (QMS)



Deviations	All deviations from what is expected, which may affect the laboratory operations and/or may pose a risk to products, patients or staff must be investigated. Corrective and preventive action must be initiated.
Test reporting	Ensure accuracy, confidentiality, and accessibility to the laboratory staff and to the health care providers.

- Immediate action to control and correct the nonconformity
- Determine the course and risk for recurrence
- Review opportunities for improvement and make changes, if needed

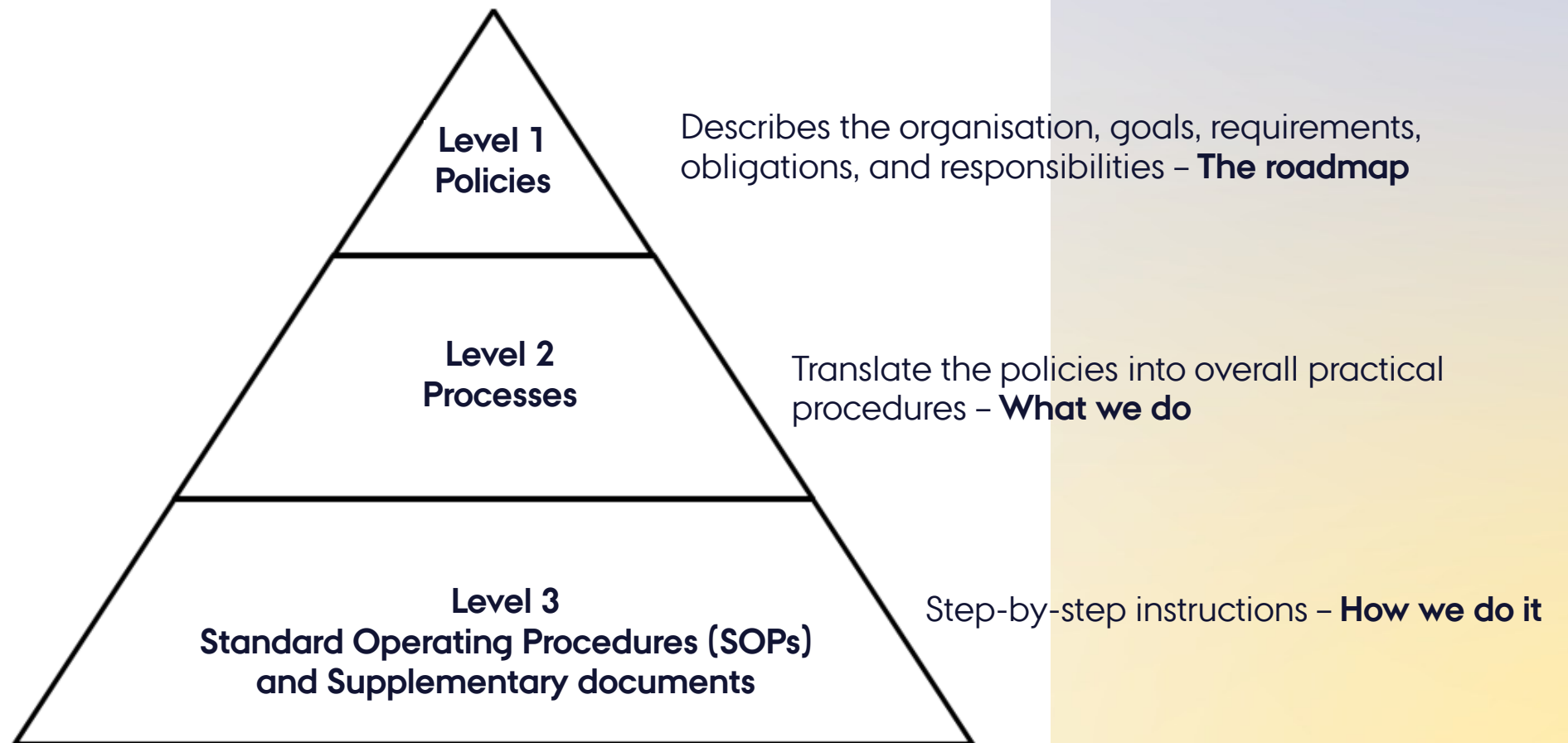


Quality Management System (QMS)



Documents and records

A system to manage documents including Standard Operating Procedures (SOPs). Good record keeping is essential to track and demonstrate traceability.

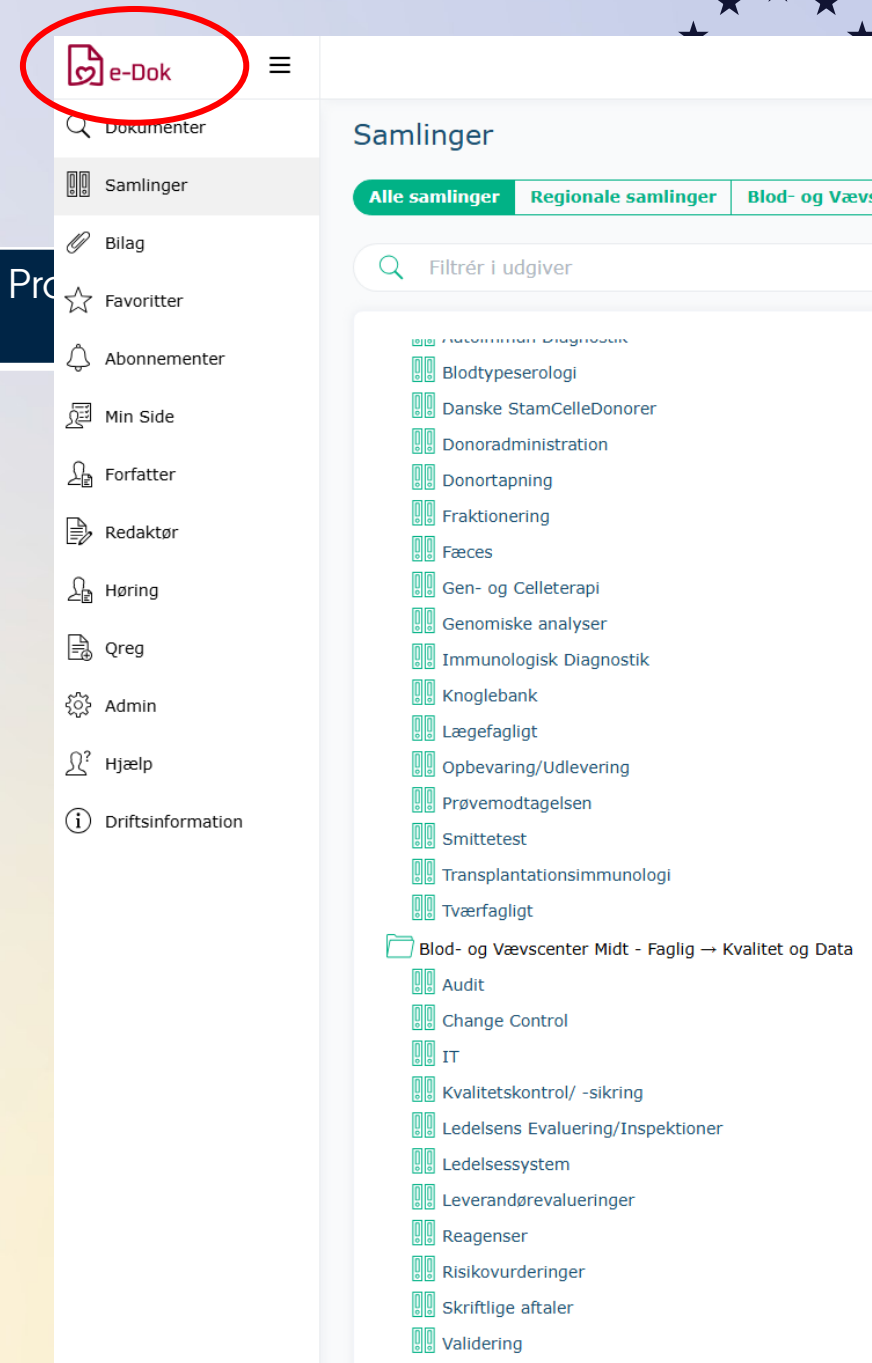
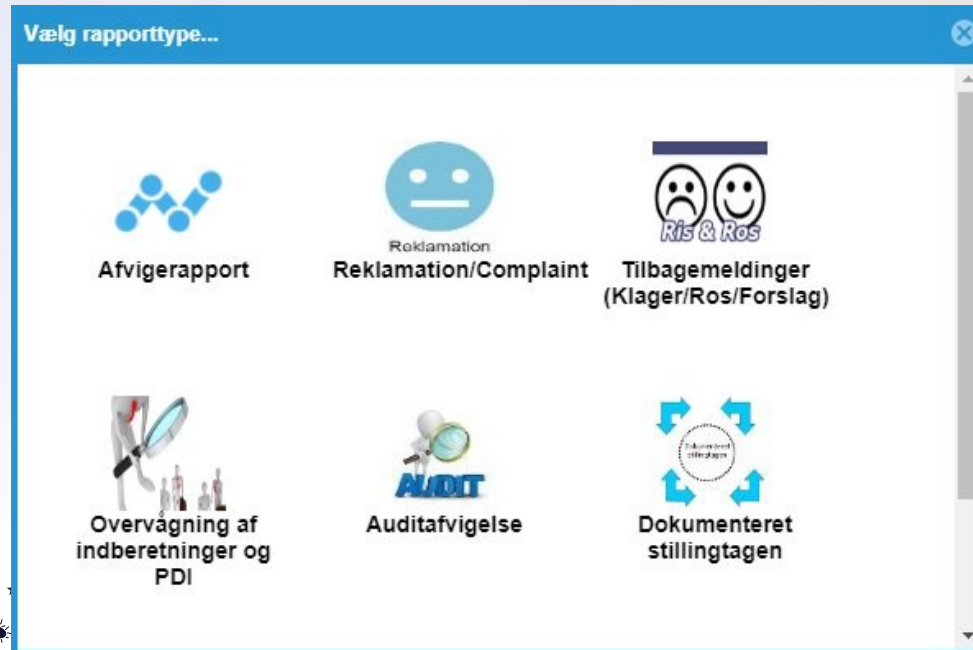


Quality Management System (QMS)

Documents and records

A system to manage documents including Standard Operating Procedures, which is essential to track and demonstrate traceability.

System for secure storage of data and records in accordance with the requirements



Quality Management System (QMS)



Documents and records

A system to manage documents including Standard Operating Procedures (SOPs). Good record keeping is essential to track and demonstrate traceability.

Documents are approved by authorized persons before use

Documents are uniquely identified and version controlled

Documents are protected from unauthorized changes, deletions or removal

Documents are available to relevant personnel

Faciliteter og rengøringsfrekvens			
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Documents are periodically reviewed and updated as necessary

Changes are clearly stated and communicated

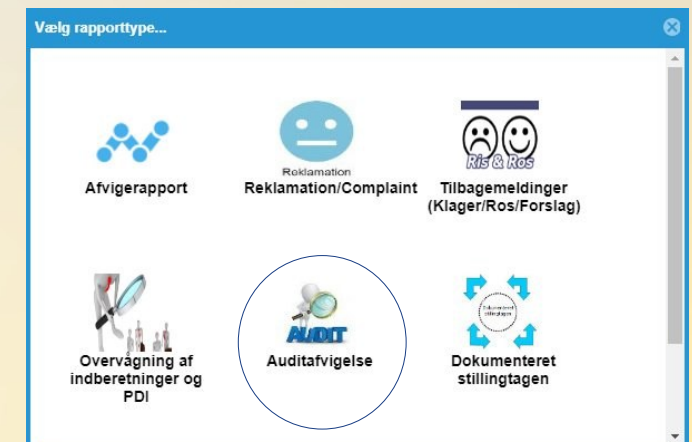
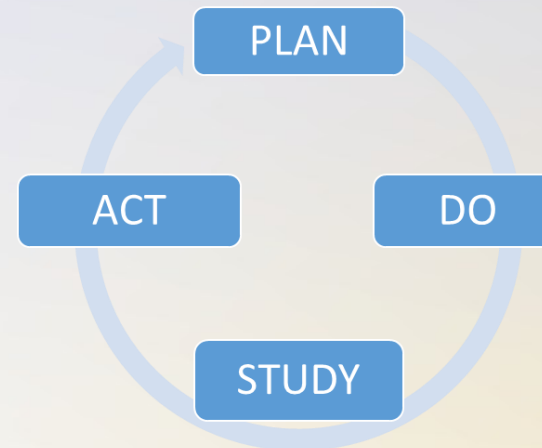
Quality Management System (QMS)



Audit and evaluation

Plans for monitoring and maintenance of the QMS by internal audits and ongoing evaluations.

- Regular self-inspections
- Evaluation of suppliers
- Audit-plan
- Audit checklist
- Audit-team
- System to report and manage audit-deviation





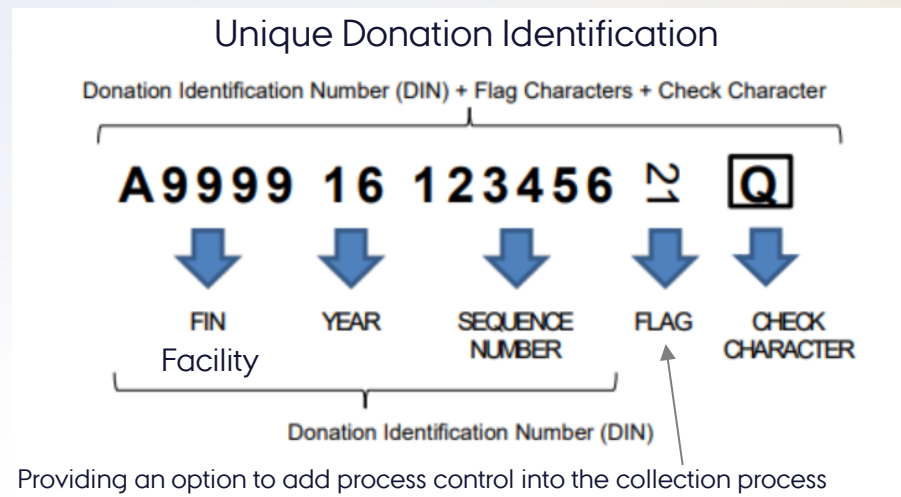
Traceability, coding, and IT systems



For end-to-end blood, cell, and tissue management, with full traceability from the donor, through production, analysis, and delivery to the recipient. ProSang tracks every step with barcode labelling in accordance with the ISBT 128 standard.



The global standard for the terminology, identification, coding and labeling of medical products of human origin (including blood, cell, tissue, and organs).



Product Description Code Database

Component Class:	RED BLOOD CELLS
Modifier:	None
Core Conditions:	Anticoagulant CPDA-1; Original volume 450 mL; Storage conditions refrigerated
Attribute:	Irradiated

Is assigned product description code E0206

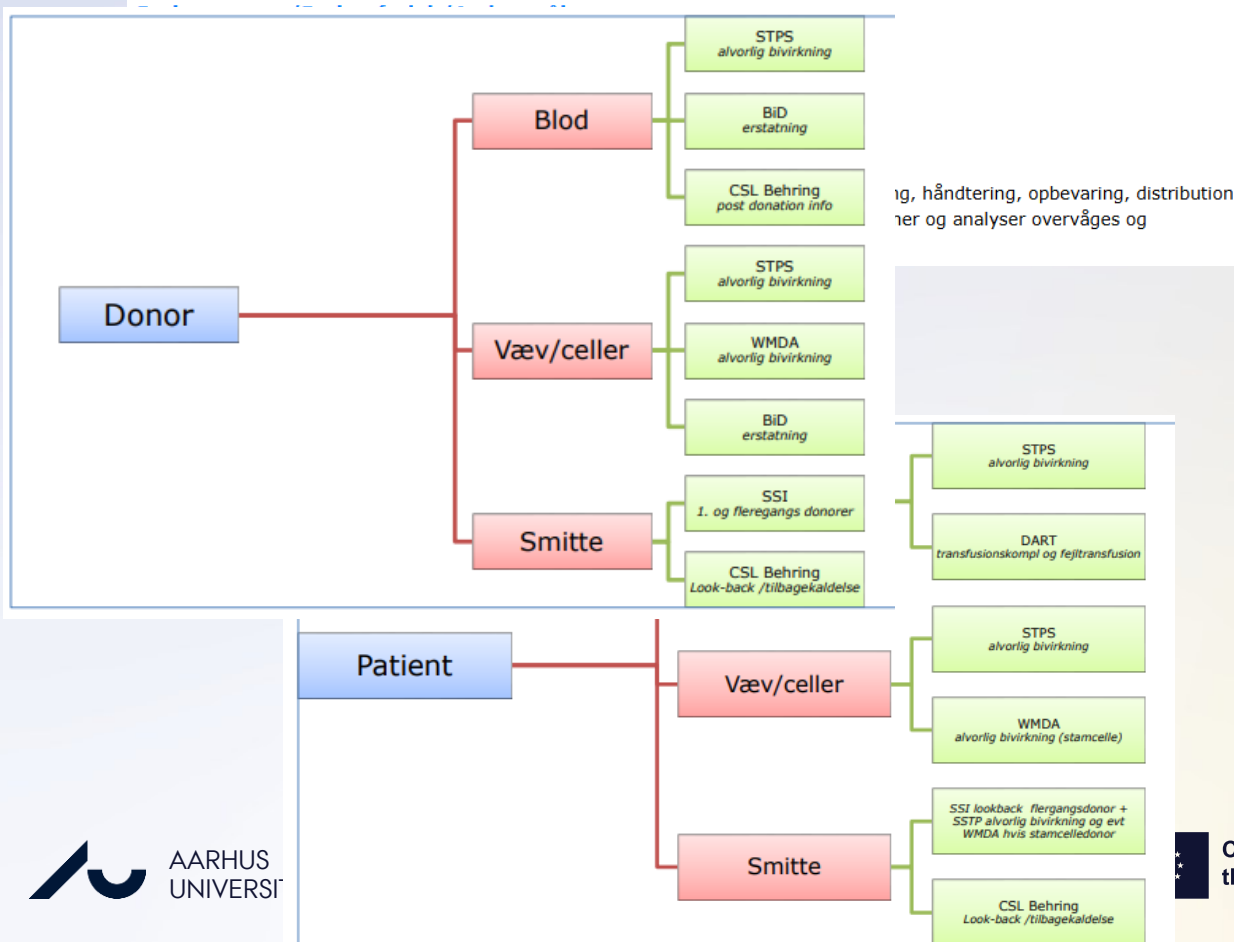
Vigilance and reporting



Registration of adverse events.

Indberetning og overvågning af bivirkninger og utilsigtede hændelser

Formål



Co-funded by the European Union



2023

DANISH HEMOVIGILANCE COMMITTEE DONORVIGILANCE REPORT



MAIN FINDINGS

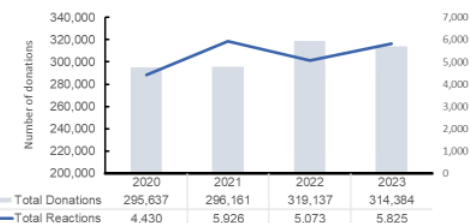
The adverse reaction rate among Danish blood donors was 1,853 per 100,000 donations (2022: 1,590 per 100,000 donations).

The overall rate of serious adverse reactions (SAR) was increased to 5.7 per 100,000 donations compared to 5 per 100,000 donations in 2022.

Of these SARs, 33% were vasovagal reactions and 34% nerve injuries.

At 838 per 100,000 donations, vasovagal reactions remained the most common adverse reaction.

Number of donations and adverse reactions



Number of adverse reactions by category

Type of reaction	2023
Hematoma	1,396
Arterial puncture	14
Delayed bleeding	237
Thrombophlebitis	<5
Deep venous thrombosis	<5
Compartment syndrome	<5
Pseudoaneurysm	0
Arteriovenous fistula	0
Direct nerve injury	89
Nerve injury caused by hematoma	39
Other arm pains	81
Vasovagal reactions	
Onsite without LOC	2,358
Onsite with LOC	220
Offsite without LOC	36
Offsite with LOC	19
Citrate reaction	104
Infiltration	1,203
Air embolism	0
Hemolysis	8
Allergy (local)	10
Anaphylaxis	0
Rare complication	<5
Other	<5
Total number	5,825
Overall rate per 100,000 donations	1,853

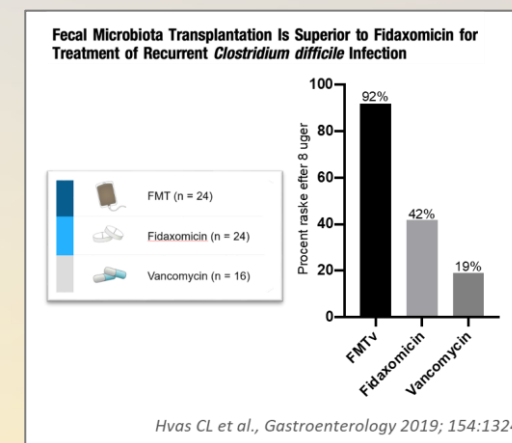
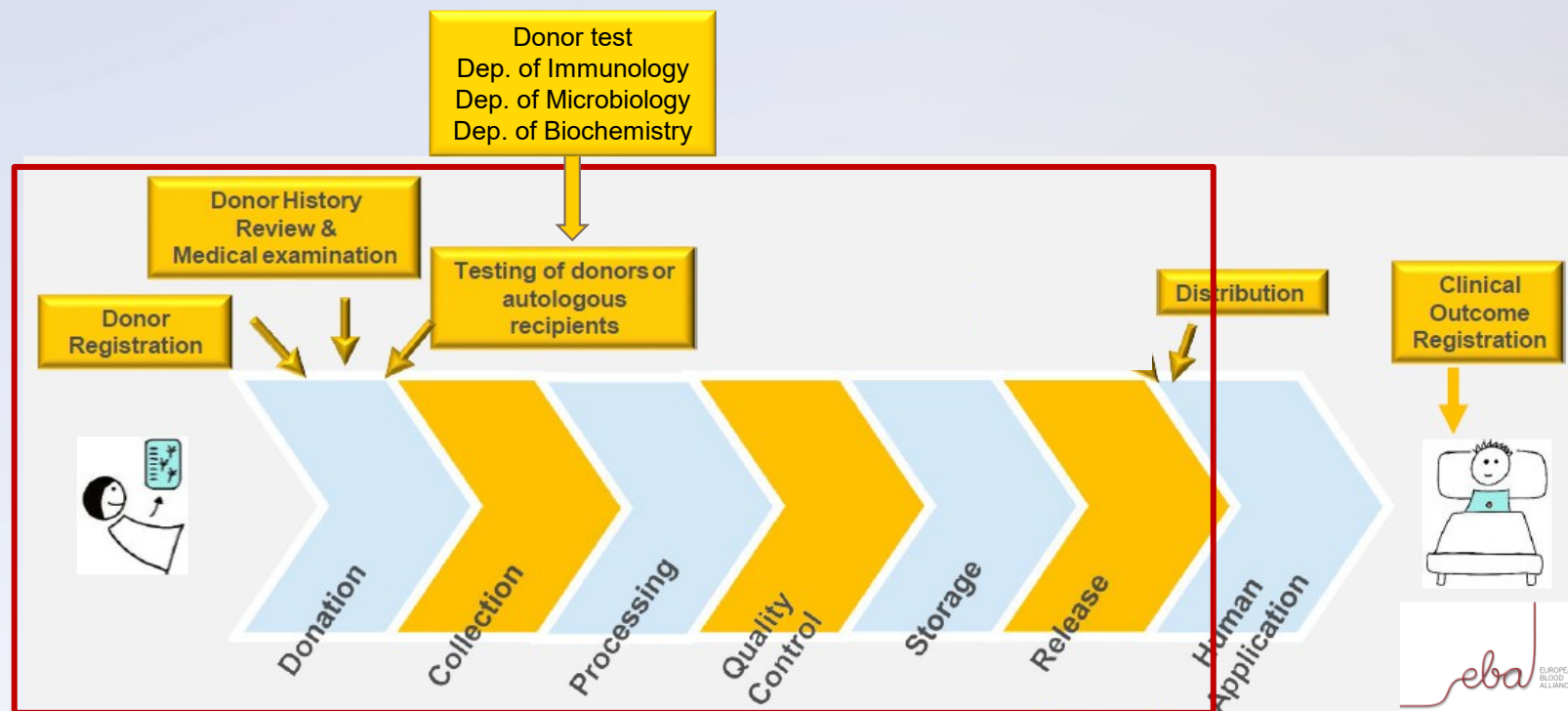
INFORMATION

Full 2023 and previous reports and guidelines

<https://dski.dk/guidelines-haemovigilance/>

✉ info@dski.dk

Implementing faeces donor recruitment, screening, and faeces processing in the blood centre facilities



GUT MICROBES
2018, VOL. 9, NO. 6, 540-550
<https://doi.org/10.1080/19490976.2018.1458179>



RESEARCH PAPER

OPEN ACCESS [Check for updates](#)

Recruitment of feces donors among blood donors: Results from an observational cohort study

Simon Mark Dahl Jørgensen , Christian Erikstrup , Khoa Manh Dinh , Lars Erik Lemming[†], Jens Frederik Dahlerup , and Christian Lodberg Hvas

Faeces donor recruitment and screening



SCANDINAVIAN JOURNAL OF GASTROENTEROLOGY
2021, VOL. 56, NO. 9, 1056-1077
<https://doi.org/10.1080/00365521.2021.1922749>



ORIGINAL ARTICLE

OPEN ACCESS [Check for updates](#)

Danish national guideline for the treatment of *Clostridioides difficile* infection and use of faecal microbiota transplantation (FMT)

Simon Mark Dahl Baunwall^a, Jens Frederik Dahlerup^a, Jørgen Harald Engberg^b, Christian Erikstrup^c, Morten Helms^d, Mie Agerbæk Juul^e, Jens Kjeldsen^f, Hans Linde Nielsen^g, Anna Christine Nilsson^h, Anne Abildtrup Rodeⁱ, Lars Vinter-Jensen^j and Christian Lodberg Hvas^k

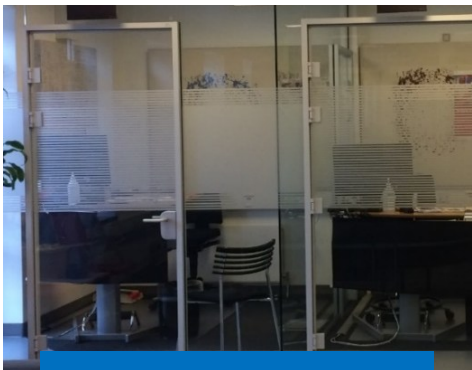


The Danish Tissue Act



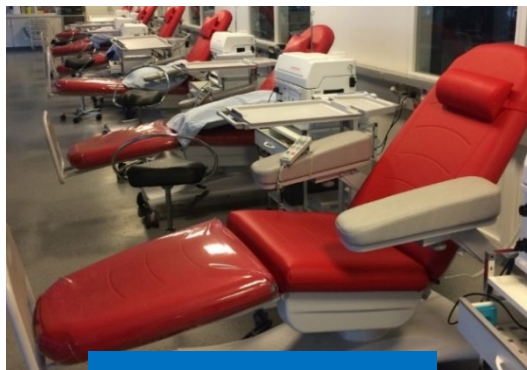
Pre-screening

Blood donor screening
Age, BMI, Medication



Donor interview

Questionnaire screening information, and consent



Blood donation

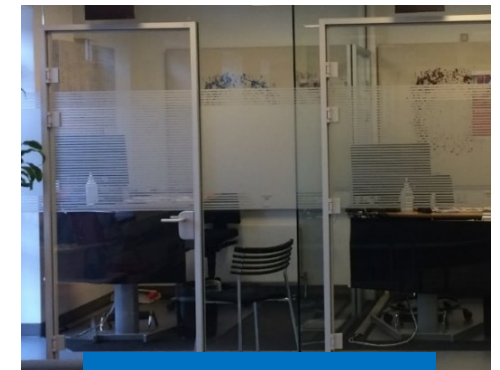
Blodprøvescreening
Biokemiske analyser (Biokemi)
Leukocyt- og differentialtælling, Hæmoglobin
Hepatitis B virus s-antigen Hepatitis B virus c-antistof Hepatitis C virus antistof
HIV 1+2 antigen-antistof Syfilis test
NAT test: Hepatitis B, Hepatitis C, HIV
Cytomegalovirus (CMV) antistof Epstein-Barr virus (EBV) antistof
Fæcesscreening
Tarmpatogene bakterier: Salmonella Yersinia enterocolitica Campylobacter jejuni Shigella Tarmpatogene E. coli Clostridium difficile
Adenovirus Enterovirus Parechovirus
Tarmpatogene parasitter: Giardia Entamoeba histolytica Cryptosporidium
Tarmpatogene parasitter (ormeæg og cyster): Mikroskopi
Screening i forbindelse med fæcesdonation: Meropenem-resistente pseudomonas aeruginosa Meropenem-resistente Acinetobacter Meropenem-resistente Enterobakterier Vancomycin-resistente Enterokokker (VRE) ESBL-producerende E.coli (Carbapenemase-producerende Enterobakterier)

Blood and faeces screening

Donor protection:

- Minimize risks related to donation
- Voluntary and unpaid donation
- Documentation of the donor health evaluation

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Approved donors




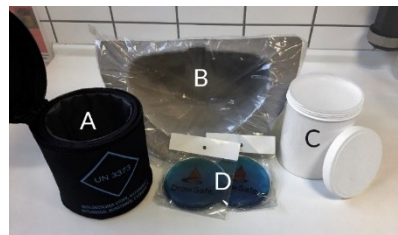
Donor approval



Faeces donation and screening

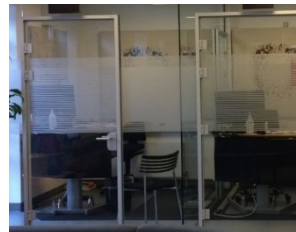
Donation of faeces takes place in donation rounds, which can last up to 30 days.

 ProSang LABORATORY INFORMATION SYSTEM			
Tappedato	Tappemåde	Kontrolprøve	Tapperesultat
10-03-2023	FMT Slut		Uden anmærkn...
08-03-2023	FMT Donation		Uden anmærkn...
24-02-2023	FMT Donation		Uden anmærkn...
13-02-2023	FMT Start		Uden anmærkn...



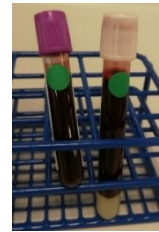
Faeces donation

Every donation



Donor interview and questionnaire screening

In the beginning and end



Blood and faecal samples



Processing, quality control, and storage

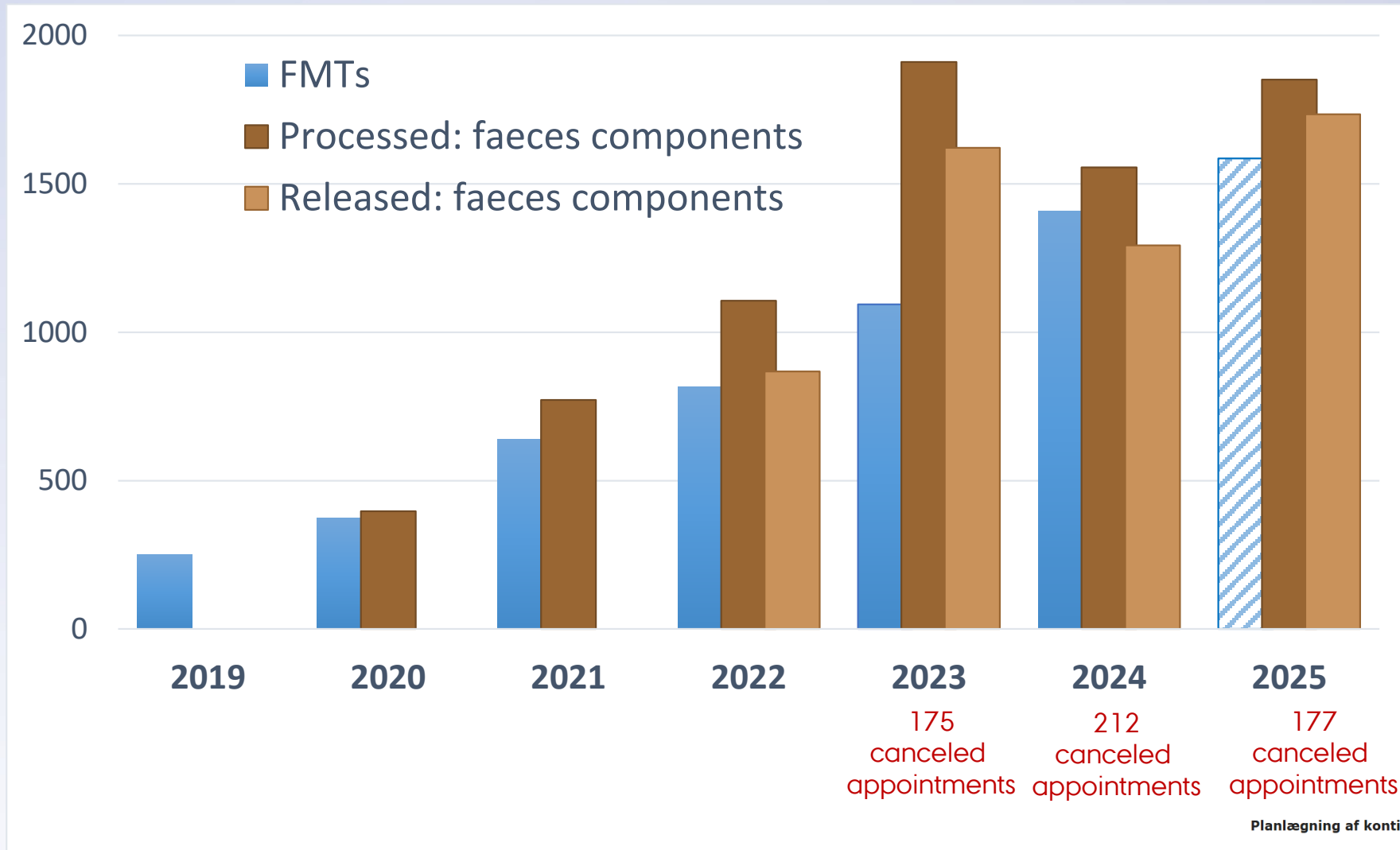
Biodprøvescreening
Biokemiske analyser (Biokemi)
Leukocyt- og differentialtælling, Hæmoglobin
Hepatitis B virus s-antigen Hepatitis B virus c-antistof Hepatitis C virus antistof
HIV 1+2 antigen-antistof Syfilis test
NAT test: Hepatitis B, Hepatitis C, HIV
Cytomegalovirus (CMV) antistof Epstein-Barr virus (EBV) antistof
Fæcescreening
Tarmpatogene bakterier:
Salmonella Yersinia enterocolitica Campylobacter jejuni Shigella Tarmpatogene E. coli Clostridium difficile
Adenovirus Enterovirus Parechovirus
Tarmpatogene parasitter:
Giardia Entamoeba histolytica Cryptosporidium
Tarmpatogene parasitter (ormeæg og cyster):
Mikroskop
Screening i forbindelse med fæcesdonation:
Meropenem-resistente pseudomonas aeruginosa Meropenem-resistente Acinetobacter Meropenem-resistente Enterobakterier

Screening results

Release

Supply continuity

A high number of positive or inconclusive microbiological tests



SoHO regulation



Supervision of all SoHo activities that directly impact safety, quality or effectiveness

