

# **The Harmonize project: Peer Audit concept**

WP4 – Milestone 8

Version 1.0

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## **PEER AUDIT CONCEPT, Harmonize FMT**

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### **Preamble**

This document describes the concept, structure, and persons involved in the peer audit program, included in work package 4 under the Harmonize FMT project, running from 01 January 2025 to 30 June 2026.

### **Contact information**

Harmonize FMT under EurFMT and EHMSG, <https://www.eurfmt.com/harmonize/>  
Aarhus University Hospital, Centre for faecal microbiota transplantation, <https://cefta.au.dk>  
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### **Context**

The Harmonize project, co-funded by the European Union, is dedicated to supporting the implementation of the new Regulation on Substances of Human Origin (SoHO) in Europe. The aim is to improve the safety, quality, and effectiveness of faecal microbiota transplantations across Europe. A core element in fulfilling this aim is the development of a structured approach to conducting peer audits across FMT centres in Europe, as defined in Work Package 4 of the Harmonize project (<https://www.eurfmt.com/harmonize/>). A structured approach could assist the European FMT centres in their preparations for inspections by national competent authorities starting beyond August 2027.

### **Aim**

The aim is to develop a structure for conducting peer audit visits in FMT centres through iterative processes, refining the content over five planned stool bank visits.

### **Colleague visits**

Five visits to established stool banks in Europe have been scheduled, including:

1. Visit 1: Leiden, The Netherlands (November 27, 2025)
2. Visit 2: Aarhus, Denmark (January 07, 2026)
3. Visit 3: Paris, France (February 26, 2026)
4. Visit 4: Rome, Italy (March 26, 2026)
5. Visit 5: Helsinki, Finland (May 06, 2026)

The focus of the visits will be to create a forum where experts in progress can meet and discuss which essential elements to include in a future peer auditing checklist. The visits can also serve as a platform for exchanging knowledge, inspiring one another to make improvements, and identifying gaps in FMT practices across Europe.

### **Peer auditors**

A group of auditors will be selected from FMT centres with prior audit experience related to the quality and safety of SoHOs. For each visit, 1–2 auditors from 2–3 different FMT centres

will be selected, resulting in a peer audit team of 2–6 auditors. The auditors must maintain objectivity and impartiality, and no auditor may take part in an audit of their own FMT centre.

Peer auditor qualifications are developed during the project. No formal requirements are formulated in the SoHO Regulation. Peer auditors should have first-degree knowledge of FMT and quality risk management. We strive for diversity in the auditor group and representation from established auditor groups in established tissue centres related to the FMT centres.

The group of auditors is further detailed in the document outlining the specific visits (Appendix 1, Visit outline).

### **Peer audit content**

The development and implementation of the peer audit concept will be based on the “guide to the quality and safety of tissues and cells for human application” issued by the EDQM, as well as the guidelines that will be developed in the framework of the Harmonize project. Furthermore, the conceptualisation will be inspired by audit practices already applied to the quality and safety of SoHOs.

In advance of the visit, the most essential documents from the audited FMT centre are sent to the peer audit team to provide an overview. A colleague visit consists of one whole day’s physical visit, typically from 9 AM to 4 PM, with the following participants:

1. Visiting auditors as outlined above
2. Hosts from the FMT centre, including representatives from all domains in the FMT centre
  - a. Donor recruitment and screening
  - b. Laboratory processing
  - c. Clinical application and follow-up

A physical “house tour” should preferably be included in the peer audit visit, in which all steps from donor recruitment to the release of the components are demonstrated and explained. Furthermore, a distinct peer audit checklist details the focus areas for the peer audit visits, with the main keywords highlighted below (Appendix 2: Peer audit checklist).

1. The quality management system
2. Donor recruitment and screening
3. Procurement and processing
4. Storage, release, and distribution
5. Coding, packaging, and labelling
6. Clinical application and follow-up
7. Traceability
8. Development plan

### **Peer audit report**

After each visit, a peer audit report will be created, documenting observations and providing suggestions for changes to the peer audit checklist. The report should at least be available for

the audited centre and the organisers of the peer audit programme at Aarhus University Hospital.

### **Iterative processes**

An iterative approach will be used to develop and refine the peer audit checklist during the five planned visits. For each visit, the following four steps will be implemented:

1. Pre-visit: Review of the materials from the host FMT centre
2. Visit: Conducting the on-site peer audit
3. Post visit:
  - a. Preparing the peer audit report
  - b. Revising and updating the checklist

Through this process, the checklist will undergo five cycles of optimisation before being finalised.

### **Reference documents**

The audit concept refers to five main documents or domains:

1. The SoHO Regulation, [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L\\_202401938](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202401938)
2. The EDQM tissues and cells guide, <https://www.edqm.eu/en/guide-to-the-quality-and-safety-of-tissues-and-cells-for-human-application1>
3. The EuroGPT II guide supplement for new substances of human origin (pending publication)
4. Published guidelines (e.g., Keller JJ et al, United European Gastroenterol J 2021; 9(2): 229).
5. Local documents (will be elaborated during the project)

### **EU milestones and deliverables in Harmonize**

1. Milestone 8:
  - a. Content: Report on the audit concept
  - b. Deadline: December 31, 2025 (month 12)
2. Deliverable D4.1:
  - a. Content: Report on the audit conduct
  - b. Deadline: June 30, 2026 (month 18)

### **Perspectives**

The conceptualisation and content development of the peer audit framework will be carried out within the scope of the Harmonize project. It is expected to be submitted for publication in autumn 2026 and will serve as a practical resource for European FMT centres preparing for future regulatory inspections.

### **Appendixes**

1. Appendix 1: Visit outline
2. Appendix 2: Peer audit checklist

## **Appendix 1**

**PEER AUDIT VISIT OUTLINE, Harmonize FMT**


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**The current group of auditors**

<b>FMT centre</b>	<b>Name</b>	<b>Position</b>	<b>Email</b>
Aarhus, Denmark	Christian Lodberg Hvas	Clinical professor, Gastroenterology	Christian.Hvas@auh.rm.dk
	Ditte Smed Kornum	Physician, Gastroenterology	dittiver@rm.dk
	Simon Mark Dahl Baunwall	Physician, Gastroenterology	simjor@rm.dk
	Susan Mikkelsen	Physician, blood center	susanmke@rm.dk
	Stine Willemann	Quality manager, blood centre	stiwil@onerm.dk
Leiden, Netherlands	Liz Terveer	Physician, Microbiology	e.m.terveer@lumc.nl
	Josbert Keller	Physician, Gastroenterology	j.keller@haaglandenmc.nl
Frankfurt/Cologne, Germany	Anastasia Tsakmaklisa	Quality manager, faeces bank	anastasia.tsakmaklis@uk-koeln.de
	Maria Vehreschild	Professor, Infectious diseases	vehreschild@med.uni-frankfurt.de
	Nina Fischer	Head of Quality Control, CMB	nina.fischer1@uk-koeln.de
	Julia Heger	Head of Production, CMB	julia.heger@uk-koeln.de
Rome, Italy	Gianluca Ianiro	Professor, Gastroenterology	gianluca.ianiro@unicatt.it
	Others?		
Paris, France	Harry Sokol	Professor, Gastroenterology	harry.sokol@aphp.fr
	Others?		
Helsinki, Finland	Perttu Arkkila	Professor, Gastroenterology	Perttu.Arkkila@hus.fi
	Heini Herranen	Study nurse	heinihe@uef.fi
	Saija Rask	Associate chief nurse	
	Annuliina Stenbacka	Tissue bank coordinator	
	Reetta Satokari	Physician, Microbiology	reetta.satokari@helsinki.fi

**Participants in the on-site peer audits**

<b>Hosting FMT centre</b>	<b>Date</b>	<b>Participants from the hosting FMT centre</b>	<b>Auditors participating from other FMT centres</b>
Leiden, The Netherlands	November 27, 2025	1. Liz Terveer 2. Josbert Keller 3. Lola Koppelman 4. ... 5. ... 6. ...	1. Anastasia Tsakmaklisa (Cologne, Germany) 2. Christian Lodberg Hvas (Aarhus, Denmark) 3. Ditte Smed Kornum (Aarhus, Denmark)
Aarhus, Denmark	January 07, 2026	1. Susan Mikkelsen (Bloodbank and immunology, Aarhus University Hospital, Denmark)	1. Ditte Smed Kornum (Department of Hepatology and Gastroenterology, Aarhus University Hospital, Denmark) 2. Christian Lodberg Hvas (Department of Hepatology and Gastroenterology, Aarhus University Hospital, Denmark)
Paris, France	February 26, 2026	1. ... 2. ... 3. ... 4. ... 5. ... 6. ...	1. ... 2. ... 3. ... 4. ... 5. ... 6. ...
Rome, Italy	March 26, 2026	1. ... 2. ... 3. ... 4. ... 5. ... 6. ...	1. ... 2. ... 3. ... 4. ... 5. ... 6. ...
Helsinki, Finland	May 06, 2026	1. ... 2. ... 3. ... 4. ... 5. ... 6. ...	1. ... 2. ... 3. ... 4. ... 5. ... 6. ...

## **Appendix 1**

**PEER AUDIT CHECKLIST, Harmonize FMT**


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**Visit date:**                    —           \_\_\_\_\_

**Visit place:**                   —           \_\_\_\_\_

**Host participants:**           —           \_\_\_\_\_

**Visitors:**                       —           \_\_\_\_\_

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Audit elements	Yes/compliant	Partially fulfilled/acceptable	Partially fulfilled/need improvement	No/not compliant	Comments
<b>01. Introduction</b>					
<p>The references included for each checklist item refer to the draft 6th edition of the <i>Guide to the Quality and Safety of Tissues and Cells for Human Application</i> issued by the EDQM, which was still under stakeholder consultation in November 2025, when the first version of this document was prepared.</p> <p>In the reference codes, “S” denotes a <i>Standard</i> in the guideline, directly linked to an article in the SoHO Regulation, while “G” denotes a <i>Good Practice Guideline</i>.</p> <p>Compliance with the SoHO Regulation requires the implementation of a quality management system. ISO 15189 is an international quality standard constituting one possible tool to support the establishment and ongoing maintenance of a quality management system (the WHO describes it here: <a href="#">WHO QMS description</a>).</p>					
<b>02. Quality management system (QMS)</b>					
Applying the QMS					
<a href="#">EDQM S2.1, S2.2</a>					
1. QMS is implemented and described in a Quality Manual	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<a href="#">EDQM G2.3, S2.20, G2.100, G2.101</a>					
2. Critical processes are defined in standard operative procedures or instructions and systematically reviewed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<a href="#">EDQM G2.6, G2.7, G2.14</a>					
3. Management and key personnel ensure systematic implementation and maintenance of the QMS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<a href="#">EDQM G2.8, G2.9, G2.10, G2.14</a>					
4. An annual review of the QMS is conducted	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<a href="#">EDQM G2.156, G2.157</a>					
Personnel and organisation					
<a href="#">EDQM S2.3</a>					
5. An organisational chart defines managerial hierarchy and staff roles	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<a href="#">EDQM G2.11</a>					
6. A documented quality policy describes organisational objectives and visions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<a href="#">EDQM G2.14</a>					
7. Key personnel are designated:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1. Responsible person ( <a href="#">EDQM S2.4, G2.17, G2.18, S2.6, S2.7</a> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2. Physician ( <a href="#">EDQM S2.8, S2.9, EDQM S2.11, S18.10</a> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3. Releasing officer(s) ( <a href="#">EDQM S2.12</a> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4. Quality manager ( <a href="#">EDQM G2.20, G2.21</a> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8. Qualifications and experience of key personnel are documented	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<a href="#">EDQM S2.5, S2.13, G2.19, EDQM G5.3</a>					
9. Delegation of tasks is documented, and is based on the competences and experience of the personnel	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<a href="#">EDQM G2.15, G2.16, S.2.10, S2.14</a>					
10. Up-to-date job descriptions describe roles, responsibilities, and competence requirements	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<a href="#">EDQM G2.12</a>					
11. A defined process exists for selection, training, re-training, qualification and disqualification of personnel	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Audit elements	Yes/ compliant	Partially fulfilled/ acceptable	Partially fulfilled/ need improvement	No/ not compliant	Comments
<p style="text-align: right;"><a href="#">EDQM G2.22, G2.24</a></p>					
12. Personnel training is documented and confirms that personnel are competent to perform their tasks <p style="text-align: right;"><a href="#">EDQM G2.13, G2.23, G2.25, G2.26</a></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
13. Periodical evaluation of personnel competences is performed <p style="text-align: right;"><a href="#">EDQM G2.27</a></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
14. A safety manual and required protective equipment are available for personnel and visitors <p style="text-align: right;"><a href="#">EDQM G2.28, G2.29, G2.30, G2.31, G2.32, G2.33</a></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Premises</b>					
15. Floor plan of used rooms and functions is available <p style="text-align: right;"><a href="#">EDQM EDQM G2.35</a></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
16. Environmental conditions (lightning, temperature, humidity, ventilation), and cleaning procedures are documented <p style="text-align: right;"><a href="#">EDQM G2.34, G2.36, G2.37</a></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
17. A structured and documented risk assessment evaluates risks of microbial contamination from environment, personnel, equipment, and materials <p style="text-align: right;"><a href="#">EDQM S9.1, S9.3, S9.5</a></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Cleaning</b>					
18. Cleaning and disinfection processes are validated or verified to confirm effectiveness <p style="text-align: right;"><a href="#">EDQM G9.43, G9.44, G9.45</a></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
19. Processing areas and reusable equipment are cleaned using sporicidal procedures before use <p style="text-align: right;"><a href="#">EDQM G33.14</a></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
20. Documented cleaning plan is implemented for the storage facility <p style="text-align: right;"><a href="#">EDQM G11.10</a></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Equipment and materials</b>					
<p style="text-align: right;"><a href="#">EDQM S2.17, S2.18</a></p>					
21. All critical equipment, materials, and software are identified and documented, including the certification status <p style="text-align: right;"><a href="#">EDQM S2.18, G2.41, G2.67, G2.70, G2.72, G2.74</a></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
22. Critical equipment, materials, and software undergo periodic qualification, validation, and performance monitoring <p style="text-align: right;"><a href="#">EDQM S2.17, S2.18, G2.42</a></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
23. Procedures exist for qualification of materials, equipment, and premises <p style="text-align: right;"><a href="#">EDQM S3.4, S3.5, G3.20-G3.26, S3.6, G3.27, G3.28</a></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
24. Purchasing processes for equipment and materials are documented <p style="text-align: right;"><a href="#">EDQM G2.45, G2.66</a></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
25. Maintenance plans exist for critical equipment, including instructions for use, cleaning, disinfection, and monitoring systems where relevant (e.g. freezer alarms and user-notifications) <p style="text-align: right;"><a href="#">EDQM G2.47, G2.50, G2.51, G2.78</a></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
26. Records of equipment maintenance activities are kept <p style="text-align: right;"><a href="#">EDQM G2.55</a></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Audit elements	Yes/compliant	Partially fulfilled/acceptable	Partially fulfilled/need improvement	No/not compliant	Comments
27. Equipment and material performance deviations are recorded and followed by corrective/preventive actions <a href="#">EDQM G2.57, G2.81</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
28. A calibration plan ensures periodic calibration of measuring equipment <a href="#">EDQM G2.61, G2.62, G2.63, G2.64</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
29. Critical materials are traceable by batch/lot number, and expiry dates <a href="#">EDQM G2.79</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Outsourced activity management <a href="#">EDQM S2.19</a>					
30. Formal agreements define outsourced activities and responsibilities of each party <a href="#">EDQM G2.84, G2.85, G2.86, G2.95, G2.96, G2.97, G2.99, G2.88, G2.94</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
31. The agreements are periodically reviewed and renewed <a href="#">EDQM G2.87</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
32. The contract giver retains or has access to relevant processing and distribution records from the contract acceptor <a href="#">EDQM G2.98</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Document-control system <a href="#">EDQM S2.20</a>					
33. A document-control system ensures periodic review, version control, and archiving of current documents <a href="#">EDQM G2.102, G2.103, G2.106, G2.107</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
34. Document changes are reviewed, dated, and approved by authorised personnel <a href="#">EDQM G2.104, G2.105</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
35. Quality-system documents are archived for at least 10 years <a href="#">EDQM G2.108</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
36. Records ensuring full traceability (donor, collection, distribution, import, export, clinical application) are maintained and stored for at least 30 years after distribution/export <a href="#">EDQM S2.21, S2.22, G109-G2.118, S17.3</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
37. Records critical to safety and quality of the FMT preparations are kept for 10 years <a href="#">EDQM G2.119</a>					
Change control <a href="#">EDQM S2.23</a>					
38. A change-control system is implemented to plan, evaluate, and document changes affecting donors or the FMT <a href="#">EDQM G2.120, G2.121, G2.122, G2.124</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
39. Revalidation/requalification is performed when significant changes occur in processes, premises, equipment, or materials <a href="#">EDQM G3.43, G3.44</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
40. Changes are approved by the responsible person or designated personnel	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Audit elements	Yes/ compliant	Partially fulfilled/ acceptable	Partially fulfilled/ need improvement	No/ not compliant	Comments
Complaints <a href="#">EDQM G2.123, G11.3</a>					
41. Procedures exist to record, assess, and manage complaints <a href="#">EDQM S2.24</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
41. Procedures exist to record, assess, and manage complaints <a href="#">EDQM S2.24, G2.127, G2.128, G2.129</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Deviations, adverse events and adverse reactions <a href="#">EDQM S2.25</a>					
42. A system exists to report, record, investigate, and correct deviations or non-compliance with the QMS <a href="#">EDQM G2.130, G2.131-G2.136</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
43. Deviations are periodically analysed to identify trends and needed corrective/preventive actions <a href="#">EDQM G2.137</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Recall <a href="#">EDQM S2.26</a>					
44. A recall procedure defines responsibilities, time limits, required actions, and authority notifications. It is regularly evaluated. <a href="#">EDQM S2.26, G2.139, G2.140, G13.17, G13.18, G13.21</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
45. Authorised personnel are available to assess and initiate the recall <a href="#">EDQM G2.138</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
46. A recall report is generated after each recall event and document the management of specific recall events <a href="#">EDQM G2.141, G2.142, G13.20</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Quality review <a href="#">EDQM S2.27</a>					
47. A quality control system ensures that no FMT is released until quality and safety have been assessed satisfactory <a href="#">EDQM G2.143, G2.144, G2.145, G2.147</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
48. A responsible person is appointed for quality-control <a href="#">EDQM G2.146</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
49. Monitoring procedures and tests confirm compliance of processing, preservation, storage methods, equipment, and reagents with acceptance criteria <a href="#">EDQM G10.57, 10.58, G10.59</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50. Quality-control results are documented <a href="#">EDQM G2.150</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
51. Quality-control test performance is regularly reviewed <a href="#">EDQM G2.148, G2.149</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
52. Quality indicators are established, monitored, and periodically reviewed <a href="#">EDQM G2.154, G2.155</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Audits					
53. A self-inspection/audit systems verifies compliance with guidelines (EDQM TC-guide) and is performed by trained, independent personnel <a href="#">EDQM G2.152</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
54. Audit non-conformities are documented and followed by corrective/preventive actions <a href="#">EDQM G2.153</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Audit elements	Yes/ compliant	Partially fulfilled/ acceptable	Partially fulfilled/ need improvement	No/ not compliant	Comments
55. Laboratory facilities performing screening tests undergo regular internal and external audits <a href="#">EDQM G7.21</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56. Inventory audits in storage facilities are performed at least annually <a href="#">EDQM G11.6</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
57. Traceability audits from donor to recipient and vice versa are implemented in the quality management plan <a href="#">EDQM G17.2</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Continuity, supply contingency and emergency planning <a href="#">EDQM S2.28</a>					
58. A continuity plan ensures maintenance of collection services, donor material, and documentation in case of temporary/permanent activity suspension <a href="#">EDQM S2.28, S2.29, S2.30, G2.158, G2.159, EDQM S2.31</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
59. Contingency and emergency plans are established, implemented, tested, and maintained <a href="#">EDQM S2.31, G2.160</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
60. Emergency procedure exists for transfer of preparations to alternative storage facilities <a href="#">EDQM G11.7</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
61. Key stakeholders and their responsibilities are defined for relevant risk scenarios <a href="#">EDQM G2.161, G2.162, G2.163</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Data registration and reporting					
62. A donor registry is implemented and maintained <a href="#">EDQM S5.14</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
63. Donation-related data are submitted yearly to the EU SoHO platform <a href="#">EDQM S5.4</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
64. Collecting activity data are submitted annually to the EU <a href="#">EDQM S8.3</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
65. The SoHO establishment collects and provides required clinical data to health authorities <a href="#">EDQM S10.15</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
66. Data on distribution/import/export are collected and included in the annual EU SoHO report <a href="#">EDQM S13.1</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
67. Data on human application are collected and reported to the health authorities <a href="#">EDQM S14.2, G14.22</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
68. SAR and SAEs are reported to the SoHO establishment and health authorities using standard documentation (also see headline 18 on biovigilance) <a href="#">EDQM G14.23, S18.3, S18.8, G18.10</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>03. Qualification, validation, and verification</b>					
69. All critical processes are validated, and all critical equipment is qualified, with documented evidence that they consistently meet predetermined quality requirements <a href="#">EDQM S3.1, G3.1-G3.15</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Audit elements	Yes/ compliant	Partially fulfilled/ acceptable	Partially fulfilled/ need improvement	No/ not compliant	Comments
70. A validation master plan defines the processes, equipment, material, personnel, and computerised systems requiring validation, including planning, execution, and documentation <a href="#">EDQM G3.16-G3.19, S3.7, S3.8, G3.29-G3.42</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>04. Risk management</b>					
71. Risk management principles are incorporated into the QMS <a href="#">EDQM G2.5</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
72. Risk assessments are documented and kept up to date <a href="#">EDQM G4.1, G4.2</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
73. Completed risk assessments are reviewed at defined intervals <a href="#">EDQM G4.3</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>05. Recruitment of potential donors, identification and consent</b>					
Donor protection <a href="#">EDQM S5.1, S5.2, S5.3</a>					
74. All donations are voluntary and unpaid <a href="#">EDQM S5.3d, S5.5-S5.8, G5.1, G33.1</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
75. Donor identity is kept confidential and not disclosed to the recipient <a href="#">EDQM S5.3h</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Donor recruitment <a href="#">EDQM S5.5-S5.9</a>					
76. Procedures exist for ethical donor recruitment, ensuring donor safety and identifying potential deceased donors <a href="#">EDQM G5.2</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
77. Donor identity is verified using at least to independent identifiers <a href="#">EDQM G5.4</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
78. A system exists to identify and refer potential deceased donors <a href="#">EDQM G5.5, G5.6</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
79. Donors receive appropriate information prior to giving consent, following national legal requirements <a href="#">EDQM S5.10, S5.11, S5.12</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
80. Procedures exist for documenting consent according to the applicable legal system <a href="#">EDQM G5.7-G5.13, G33.1</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>06. Donor evaluation</b>					
81. Donor selection and evaluation procedures are in place <a href="#">EDQM S6.1, S6.2, G6.2, G33.1</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
82. Donor selection criteria are established and regularly updated by the responsible physicians <a href="#">EDQM G6.1, G16</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
83. Interviews and questionnaires are completed to assess donor eligibility <a href="#">EDQM S6.3, G6.5, G6.11, G33.1</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
84. The clinician in charge reviews the complete donor record before approval <a href="#">EDQM G6.10</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Audit elements	Yes/compliant	Partially fulfilled/acceptable	Partially fulfilled/need improvement	No/not compliant	Comments
85. Procedures exist for the clinicians to handle deviations during donor evaluation <a href="#">EDQM G6.19-6.30</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
86. A donation-specific questionnaire is completed at each donation, covering changes since previous approval <a href="#">EDQM G33.3</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>07. Screening for markers of transmissible infections</b>					
87. A donor screening program is implemented (blood and faeces) <a href="#">EDQM S7.1, S7.2, S7.3, G7.1, G33.1</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
88. Blood screening samples are adequately labelled to ensure the link between the sample, the donor and the donation <a href="#">EDQM G7.4, G7.5</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
89. Blood samples and faeces samples are performed at the start and end of a donation period <a href="#">EDQM G7.9, G7.11, G33.1, G33.5</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
90. The donation period has a defined maximum duration, not exceeding three months <a href="#">EDQM G33.4</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
91. FMT specific testing is performed (Chapter 33, Tabel 33.1) <a href="#">EDQM G33.2</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
92. Reagents and screening assays comply with the Medical Device Regulation (EU) 2017/746 <a href="#">EDQM S7.5</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
93. Tests and reagents used for donor testing are validated and verified <a href="#">EDQM G7.24, G7.25</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
94. Method suitability test is performed for the microbial test methods (specificity, sensitivity, and robustness) <a href="#">EDQM G12.22-G12.29</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
95. Standard operative procedures exist for laboratory handling and re-testing of screening samples <a href="#">EDQM G7.23, G7.26, G7.27, G7.28, G7.29</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
96. Procedures ensure prompt communication of screening results, including immediate alerts for positive findings <a href="#">EDQM G7.30, G7.31, G732</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
97. Data security measures prevent unauthorised deletions, modifications, or addition of results <a href="#">EDQM G7.33</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
98. Standard operative procedures define acceptance/rejection for donations based on the test results. Preparations contaminated with specific pathogens are discarded. <a href="#">EDQM G7.34, G12.30-31</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
99. FMTs prepared during a donation period are quarantined until full validation and post-donation screening results are available <a href="#">EDQM G33.6, G33.7</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
100. A donor management policy exists for informing donors and managing follow-up after confirmed positive results	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Audit elements	Yes/ compliant	Partially fulfilled/ acceptable	Partially fulfilled/ need improvement	No/ not compliant	Comments
EDQM G7.36, G7.38					
101. Access to microbiology laboratory services and guidance from a qualified expert microbiologist is ensured	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
EDQM G12.1					
<b>08. Collection</b>					
Introduction					
102. The organisation in charge of collection of SoHOs is registered	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
EDQM S8.2					
Collection facilities					
103. Collection facilities have appropriate size, air quality, cleanliness, and division in different areas	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
EDQM G8.3, G8.5, G8.6, S9.2					
104. Records demonstrate qualification and ongoing monitoring of the collection-site processing area	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
EDQM G8.22					
105. A risk assessment confirms suitability of collection facilities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
EDQM G8.4					
Donor identification and collection procedures					
106. Donor identification procedures are implemented	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
EDQM G8.8, G8.9					
107. Measures are taken to ensure that the donated faeces are fresh and derived from the particular donor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
EDQM G33.8					
108. Each donor is assigned a unique identifier	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
EDQM G8.10					
109. Standardised collection procedures, including protection of donor safety	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
EDQM G8.11					
110. Procedures and policies exist to minimise the risk of microbial contamination	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
EDQM G8.12, G8.13					
Tissue packaging, coding, and temporary storage					
111. Clean, pathogen-free, faecal containers appropriate for transportation of human material are used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
EDQM G33.9, G33.10					
112. Records verify compliance with required storage conditions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
EDQM G8.27, G8.28					
Documentation					
113. Collection reports document donor identifier, donation type, donor details, responsible staff, date/time/location, and any incidents of collection, and any potential incidents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
EDQM G8.29-G8.39					
<b>09. Premises, equipment, and cleaning</b>					
Placed under headline 02, QMS					
<b>10. Processing</b>					
Receipt of the donation					
114. Procedures ensure donations are quarantined until inspected/verified by authorised staff	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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<b>EDQM S10.1, G10.1, G10.2, G10.3, G10.4, G10.5</b>					
115. Transport conditions, packaging, and labelling are verified on receipt <b>EDQM G10.5, G10.6</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
116. Procedures exist for managing donations with incomplete test results <b>EDQM G10.7</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Processing methods</b>					
117. Measures prevent disease transmission through cross-contamination during processing, including avoidance of physical contact between donations <b>EDQM S10.2, 10.4, 10.5</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
118. Processing steps impacting FMT quality and safety are validated/verified and carried out under controlled conditions <b>EDQM G10.12, G10.13</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
119. All processing activities are documented in a processing record <b>EDQM G10.15, G10.16, G10.21, G33.18</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
120. Time interval between collection until processing and storage are defined <b>EDQM G10.29</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
121. Faeces are processed within six hours after defaecation <b>EDQM G33.12</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
122. If not processed immediately, faeces donations are stored at 2-8 °C until processing <b>EDQM G33.13</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
123. A visual inspection of the donated faeces confirms consistency and absence of blood and urine <b>EDQM G33.11</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
124. Archive samples of fresh and processed faeces are kept for at least one year after application (look-back, quality improvement, and investigation of adverse events) <b>EDQM G33.16, G33.17</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
125. Sampling is performed at least once before placing the FMT in the final package <b>EDQM G12.3, G12.11-G12.20</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
126. Acceptance, rejection, or disposal of the FMT preparations is documented <b>EDQM G10.31</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
127. All reagents used during processing are CE marked, or a risk-assessment is performed if not <b>EDQM G10.33, G10.34</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
128. Preservation methods are validated to maintain critical FMT properties for the full storage duration <b>EDQM G10.44</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Preparation authorisation</b>					
129. A preparation authorisation application is submitted to the national competent authority <b>EDQM S10.8, S10.9-S10.14, G10.55, G10.56</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>11. Storage</b>					
General considerations					

Audit elements	Yes/compliant	Partially fulfilled/acceptable	Partially fulfilled/need improvement	No/not compliant	Comments
130. Maximum storage time and conditions are defined and validated <a href="#">EDQM G11.1</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
131. Faecal preparations are stored at -80 °C (up to two years) <a href="#">EDQM G33.21, G33.22</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
132. Storage at -20 °C should not exceed four weeks. Storage at 2-8 °C in relation to application should not exceed six hours. <a href="#">EDQM G33.23, G33.24</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
133. System in place to separate released, quarantined, and rejected preparations <a href="#">EDQM G11.2</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
134. Storage materials are qualified for the designated storage conditions <a href="#">EDQM G11.4</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Storage facilities <a href="#">EDQM S11.3</a>					
135. Storage areas are clean, secure, appropriately sized, dedicated, and restricted to authorised personnel only <a href="#">EDQM G11.9, G11.11</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
136. Alarm system in place to detect deviations from predefined storage conditions (24-hour basis) <a href="#">EDQM G11.14</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
137. Back-up storage equipment or alternatively a back-up energy source is available <a href="#">EDQM G11.15, G11.16</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Documentation					
138. Storage reports document location, storage/removal date, temperature, incidents <a href="#">EDQM G11.20</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Disposal of human tissues and cells					
139. SOP exist for disposal of discarded preparations in compliance with national legislation <a href="#">EDQM G11.21, G11.22</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
140. Disposal records document date of disposal, personnel, and reasons for disposal <a href="#">EDQM G11.23</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>12. Microbiology</b>					
Points placed under headline 07 and 10					
<b>13. Release, distribution, and import/export</b>					
Release					
141. Minimum acceptance criteria for the preparation are defined <a href="#">EDQM G2.151</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
142. Release is performed by a releasing officer after documented review of collection, processing, and storage records <a href="#">EDQM S13.2, G13.1-G13.3, G33.1</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Distribution					
143. Distribution only occurs upon prescription from a clinician or another authorised person <a href="#">EDQM G13.7, G13.8</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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144. Written shipment agreements exist between the shipping entity and the tissue establishment <a href="#">EDQM G13.10</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
145. Transportation conditions are defined and comply with laws and regulations on transportation of biological substances <a href="#">EDQM G13.11-13.14</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
146. Access to data on pick-up and delivery of the TCP from the courier to ensure traceability <a href="#">EDQM G13.15</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
147. Distribution records are available <a href="#">EDQM G13.15, G13.16</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Import and export</b>					
148. SoHO establishments holds authorisation from their Health Authority to import <a href="#">EDQM S13.10</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
149. Written agreements with third-country suppliers define roles, transport, packaging, and shipment <a href="#">EDQM S13.11, G13.27</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
150. Receiving establishment examines packaging, labelling, transport conditions, and traceability upon receipt (a document should describe this procedure) <a href="#">EDQM S13.12, S13.13, S13.14, G13.22-G13.28, G14.4, G14.5</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>14. Interaction between SoHO establishments and organisations responsible for human application</b>					
151. The organisation responsible for human application (ORHAs) are registered with the Health authorities before carrying out human application of FMT <a href="#">EDQM S14.1</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
152. Recipient consent is received and documented (national legislation followed) <a href="#">EDQM S14.7</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
153. Storage of received FMT at the OHCA are following the storage guidance in the supplying SoHO establishment <a href="#">EDQM G14.6, G14.7, G14.8-G14.11</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
154. An electronic or paper log of all FMT components are received, stored, used, or discarded <a href="#">EDQM G14.18</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
155. The FMT treatment is documented in the patient record <a href="#">EDQM G14.19</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
156. FMT are considered for recurrent, fulminant, and refractory C. difficile infections <a href="#">EDQM G33.25, G33.26</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
157. Patients with C. difficile infections are receiving pretreatment with C. difficile-specific antimicrobials for at least three days and until 12-48 hours before FMT <a href="#">EDQM G33.27</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
158. The FMT preparations are kept at room temperature when applied to the patients <a href="#">EDQM G33.31</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
159. Thawed preparations are used the same day and not refrozen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Audit elements	Yes/ compliant	Partially fulfilled/ acceptable	Partially fulfilled/ need improvement	No/ not compliant	Comments
<p style="text-align: right;"><a href="#">EDQM G33.32</a></p> 160.The faecal preparations are administered into the right colon during colonoscopy. Upper gastrointestinal administrations are administered with the recipient placed in an upright position	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<p style="text-align: right;"><a href="#">EDQM G33.34, G33.35</a></p> 161.Capsules are visually inspected before application, and discarded if visible cracks are observed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<a href="#">EDQM G33.36</a>					
<b>15. Computerised systems</b>					
<p style="text-align: right;"><a href="#">EDQM S15.1, G15.3</a></p> 162.Technologies are implemented to reduce the risk of human errors where possible	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<p style="text-align: right;"><a href="#">EDQM G15.1, G15.2, G15.7, G15.8</a></p> 163.Hardware and software are protected against unauthorised access or changes, and back-up procedures prevent data loss	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<p style="text-align: right;"><a href="#">EDQM S15.2, G15.4</a></p> 164.Software, hardware, and back-up procedures are validated or qualified	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<p style="text-align: right;"><a href="#">EDQM G15.6</a></p> 165.Maintenance plans for computerised systems are documented and implemented	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>16. Coding, packaging, and labelling</b>					
Coding					
<p style="text-align: right;"><a href="#">EDQM S16.1, S16.2, S16.3-S16.6</a></p> 166.Unique, machine-readable, non-identifying code is applied to labels or accompanying documents, compliant with SEC rules.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<p style="text-align: right;"><a href="#">EDQM G16.1</a></p> 167.A coding system (EUTC, ISBT128 or Eurocode) is implemented for traceability	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<p style="text-align: right;"><a href="#">EDQM G16.2, G16.3, G16.4</a></p> 168.Each donation receives a unique donation code, ensuring traceability to the donor within all stages from donor identification to clinical application/disposal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Packaging					
<p style="text-align: right;"><a href="#">EDQM G16.5, G16.6, G33.20</a></p> 169.Storage packaging is appropriate for cryopreservation, freezing, transportation, transport of biologic materials, and preventing leakage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<p style="text-align: right;"><a href="#">EDQM G33.19</a></p> 170.The primary packaging, including bags and syringes are suitable for liquid intestinal microbiota preparations, while acid-resistant capsules are used for orally administered encapsulated FMT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Labelling					
<p style="text-align: right;"><a href="#">EDQM G16.10</a></p> 171.Labelling procedures are documented	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
172.Labels adhere firmly to the container, are clear, indelible, unique, unambiguous, and ideally barcode-based	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Audit elements	Yes/ compliant	Partially fulfilled/ acceptable	Partially fulfilled/ need improvement	No/ not compliant	Comments
<p style="text-align: right;"><a href="#">EDQM G16.9, G16.11-G16.17, G16.24</a></p>					
173. Accompanying tissue or blood samples for testing are accurately labelled with donor ID, and date, time, and place of sampling <p style="text-align: right;"><a href="#">EDQM G16.18</a></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
174. Labelling should occur at collection: if container space is limited, information is included in a separate accompanying document <p style="text-align: right;"><a href="#">EDQM G16.19, G16.20</a></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
175. Accompanying documents are packed with the primary container in a way ensuring they remain together <p style="text-align: right;"><a href="#">EDQM G16.25</a></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>17. Traceability</b>					
176. A traceability system links each donor to all associated FMTs, documents, and samples <p style="text-align: right;"><a href="#">EDQM S17.1</a></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
177. The traceability system identifies both donor, recipient, and all related quality and safety data <p style="text-align: right;"><a href="#">EDQM S17.2</a></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
178. Responsibilities for traceability are defined and documented <p style="text-align: right;"><a href="#">EDQM G17.1</a></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>18. Biovigilance</b>					
179. System exists for detecting, communicating, receiving, investigating, and recording adverse reactions/events <p style="text-align: right;"><a href="#">EDQM S14.10, S18.2, S14.12, S18.4, S18.6</a></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
180. SAR and SAEs are reported to the SoHO establishment and health authorities without undue delay using standard documentation <p style="text-align: right;"><a href="#">EDQM G14.23, S18.3, S18.8, G18.10</a></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
181. Procedure exists for reporting SAREs in a timely manner to the responsible person at the SoHO establishment and the health authorities. SAREs are investigated, alerted, and resolved immediately <p style="text-align: right;"><a href="#">EDQM G18.2</a></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
182. A biovigilance coordinator is appointed <p style="text-align: right;"><a href="#">EDQM G18.3</a></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
183. A follow-up system is documented in a standard operative procedure <p style="text-align: right;"><a href="#">EDQM G18.4</a></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
184. Rapid quarantine/recall procedures and look-back mechanisms are implemented <p style="text-align: right;"><a href="#">EDQM G14.20, G14.21, G14.25, G14.26, G14.27, S18.5, S18.9, G18.8, G18.11</a></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
185. Health professionals receive training on identifying and reporting SARE without undue delay <p style="text-align: right;"><a href="#">EDQM G14.24, G18.13, G18.14</a></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>19. Development plan</b>					
186. Strategy meetings with specific intervals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
187. Teaching activity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
188. Research activity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Issues to follow-up	Responsible person	Comments
1.		
2.		
3.		
4.		
5.		
6.		
7.		

\* An electronic follow-up document containing the essential documents from the FMT centre should preferably be provided to the audit team before the visit.

**Co-signed by hosting and visiting colleagues (date, place, name, signature)**

\_\_\_\_\_   
 Host institution

\_\_\_\_\_   
 Visiting institution