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Nota di contenuto	Chapter 1. Management of Biobanks -- Chapter 2. Quality Management -- Chapter 3. Documentation and Records -- Chapter 4. Human Resources Management -- Chapter 5. Ethical and Legal Aspects -- Chapter 6. Supplies, Materials Management -- Chapter 7. Equipment -- Chapter 8. Traceability -- Chapter 9. Environmental and Staff Hygiene -- Chapter 10. Biobanking Processes and Quality Control -- Chapter 11. Deviations, Nonconforming Product/Data or Service -- Chapter 12. Audits -- Chapter 13. Improvement -- Chapter 14. Biobank Cooperation in the Scientific, Research and Development Area -- Chapter 15. Safety and Security.
Sommario/riassunto	This pioneering handbook serves as an essential tool for any biobanking entity to create, implement and continuously improve their Quality Management System (QMS). Written in a concise and highly readable manner all biobanking related QMS aspects, ranging from legal aspects to safety matters, are addressed according to the best knowledge in compliance with the dedicated Biobanks ISO standards. Following a practical approach by making use of FAQ and common practice sections this book guides the readers through this complex field in an easy-to understand way. The guidelines are convergent not only with ISO 20387:2018 Biotechnology - Biobanking - General requirements for biobanking but also with ISO 9001:2015, ISO 19011: 2018, ISO 27000:2014, and ISO 27002:2013. Furthermore, they are

compatible, among others with the recommendations of the Organization for Economic Cooperation and Development (OECD), IARC, and ISBER Best Practices. Aimed at both biobank employees and other stakeholders (e.g. public bodies, political bodies, hospitals, pharmaceutical industry, funders) at any level of experience the book serves as valuable source for self-education and teaching. The manual complies to the principles of responsibility, openness, and transparency and can be used by any biobanking unit regardless of the biological material the biobank operates with and independent of their associated biobank network. On behalf of a group of specialists and experts in the area of biobanking, regarding Quality Management Systems (QMS), Ethical, Legal and Societal Issues (ELSI) and IT solutions, the authors present with this book a significant achievement based on activities within the project, European Research Infrastructure BBMRI-ERIC „Quality Standards for Polish Biobanks” Handbook (QSPB).
