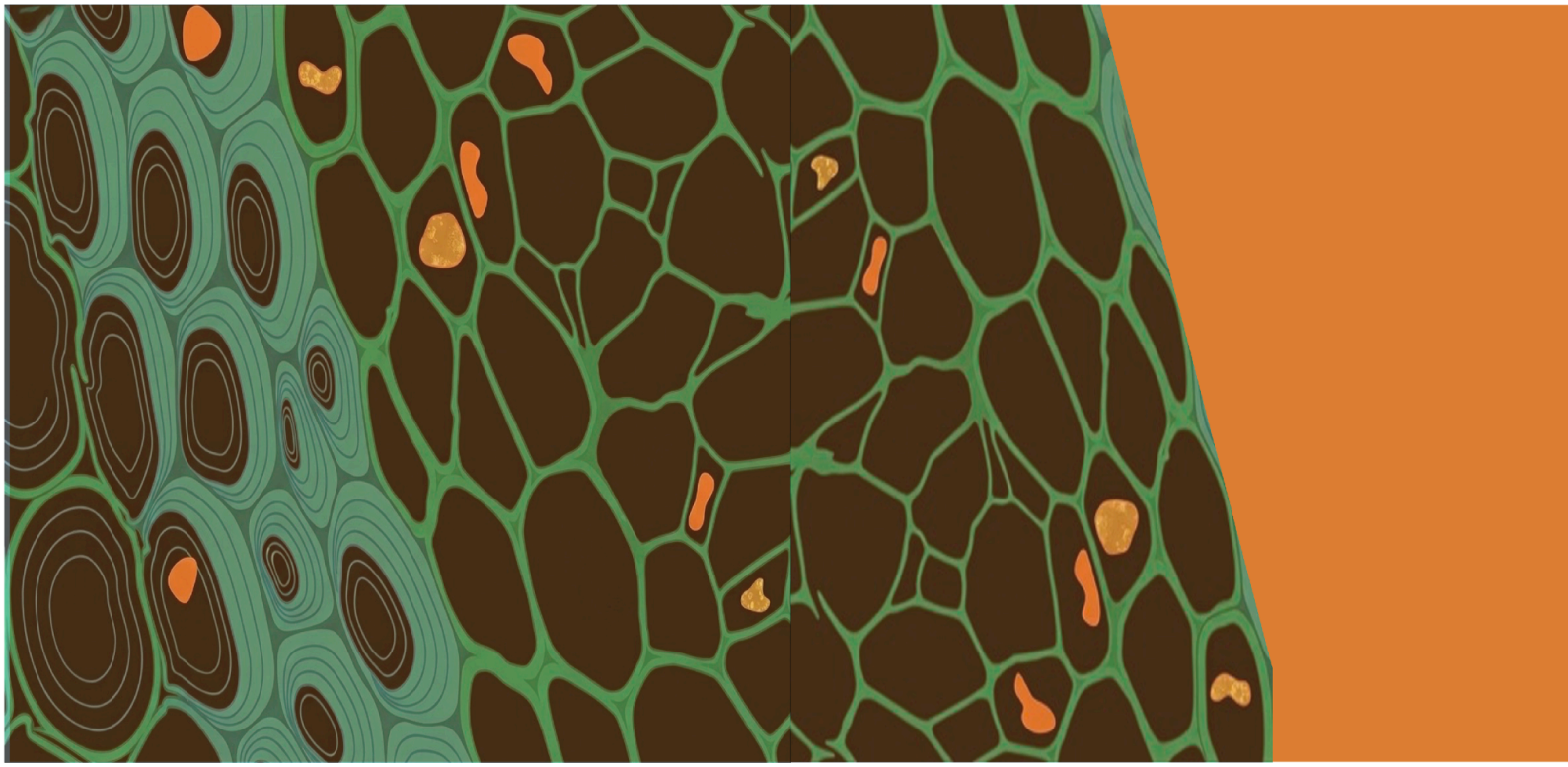

BOOK OF ABSTRACTS

NANOMED SUMMER SCHOOL
MEDICAL TISSUE ENGINEERING

University of Pavia,
room Dompé, Polo Didattico
Department of Drug Sciences
Piazza Volontari del Soccorso, Pavia

20-22 July 2026

Scientific Committee

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Prof. Bice Conti
Prof. Rossella Dorati
Dr. Silvia Pisani
Prof. Silvia Rossi
Prof. Giuseppina Sandri

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UNIVERSITÀ DI PAVIA
Department of Drug Sciences

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PROGRAM

July 20th 2026		Section chair
9.00 – 9.30	Registration	
9.30 – 9.45	Institutional welcome	
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10.30 – 11.30	Prof. Sara Perteghella, Dept. of Drug Sciences, University of Pavia, Pavia, Italy *Advanced therapy medicinal products: Overview*	Prof. Carla Caramella
11.30 – 12.00	Prof. Umberto Musazzi, Dept. of Pharmaceutical Sciences, University of Milan, Milan, Italy *When tissue engineering becomes a medicine: Regulatory perspectives on ATMPs*	
12.00 – 12.30	Dr. Zoe Giorgi, Regenera Srl/ Dept. of Chemistry, Materials and Chemical Engineering "Giulio Natta", Politecnico di Milano, Milan, Italy *Case study - Spinosave®: A point-of-care TEP strategy for acute spinal cord injury*	
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16.30 – 17.30	Prof. Ing. Stefania Marconi, Dept. of Civil Engineering and Architecture, University of Pavia, Pavia, Italy *Additive manufacturing technologies for tissue engineering (visit to 3D4Med)*	
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10.30 – 11.30	Dr. Deborah Bertorello, RiMS, Rehabilitation in Multiple Sclerosis, Brussels, Belgium *Bridging science and society in bio-nanotechnology: The TEN4CARE journey*	
11.30 – 12.30	Dr. Beatrice Lucia Bona, Dept. of Medical Biotechnology and Translational Medicine, University of Milan, Milan, Italy *Thermoplastic biomaterials for tissue engineering and regeneration*	
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15.20 – 16.10	Dr. Hussein Genedy, Regenerative Medicine and Skeleton, RMeS, UMR1229, Nantes Université, Nantes, France *Nanomedicine for tissue regeneration: Nanoparticles as tools and carriers*	
16.10 – 16.40	**Break**	Proff., Giuseppina Sandri and Silvia Rossi
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9.00 – 9.40	Dr. Angel Del Pozo, Biokeralty Research Institute AIE, Miñano, Spain *What's next: The use of knowledge in research*	Proff., Giuseppina Sandri and Silvia Rossi
9.40 – 10.20	Dr. Gabriele Maria Fortunato, Dept. of Information Engineering and Research Centre " E. Piaggio", University of Pisa, Pisa, Italy *Electrospinning as a powerful tool for tissue engineering applications*	
10.20 – 10.40	**Break**	
10.40 – 11.20	Giulia Magri, Quality & Regulatory Affairs Director, Confindustria Dispositivi Medici, Milan, Italy *Regulatory of medical devices*	Prof. Bice Conti
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VENUE

Room Dompé, Polo Didattico, Department of Drug Sciences, University of Pavia, Piazza Volontari del Soccorso.

The mission of the Department of Drug Sciences (DSF) is to bridge the gap between scientific discovery and healthcare solutions. Our researchers collaborate across key innovative sectors—including Pharmaceutical Chemistry, Biotechnology, Pharmacology, and Food Chemistry—to advance the development of next-generation drugs.
Together with our global academic and industrial partners, DSF is pioneering the future of pharmaceutical innovation.

Find it on Google Maps

ABSTRACT INDEX

L-1 | Advanced therapy medicinal products: Overview

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Advanced Therapy Medicinal Products (ATMPs) represent a paradigm shift in modern pharmacology, offering innovative therapeutic options based on genes, tissues, or cells to address previously untreatable diseases and injuries. This lecture provides a comprehensive overview of ATMPs from a Pharmaceutical Technology perspective.

The session will systematically dissect the European regulatory framework (Regulation EC No 1394/2007) governing the classification of these products into gene therapies, somatic cell therapies, and tissue-engineered products. Key technological milestones will be explored, contrasting traditional cell therapies with scaffold-based tissue engineering approaches.

Special focus will be placed on the critical role of mesenchymal stem cells (MSCs) and their primary sources, such as bone marrow and adipose tissue.

Additionally, the lecture will address the stringent manufacturing requirements under Good Manufacturing Practice (GMP), detailing essential quality control, characterization parameters (identity, purity, potency, safety), and translational aspects including cell encapsulation technologies.

L-2 | When tissue engineering becomes a medicine: Regulatory perspectives on ATMPs

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Medicinal products are commonly associated with conventional drugs, such as small molecules or biological products. However, within the European regulatory framework, a medicinal product may also be based on living cells, tissues, or nucleic acids when these are used to treat, prevent, or diagnose disease, or to restore, correct, or modify physiological functions. Advanced therapy medicinal products (ATMPs) therefore extend the concept of medicinal product to therapies in which the active substance may consist of such biological entities, requiring a dedicated regulatory framework. According to Regulation (EC) No 1394/2007, ATMPs include gene therapy medicinal products, somatic cell therapy medicinal products, and tissue-engineered products. Tissue-engineered products are defined as products that contain or consist of engineered cells or tissues and are intended to regenerate, repair, or replace human tissue.

This lecture will provide an introductory overview of the European regulatory framework for ATMPs, with a specific focus on tissue engineering. Starting from the legal definition of a medicinal product, it will clarify the distinction between organ and tissue transplantation and ATMPs, emphasizing when cells or tissues become regulated as medicinal products.

Particular attention will be given to key classification criteria, including substantial manipulation, non-homologous use, the intended function of the product, the relevance of additional components, such as devices, in regulatory qualification, and the conditions under which an ATMP may be considered a combined ATMP. The aim is to provide PhD students with a clear conceptual framework for understanding how tissue engineering approaches are translated into regulated medicinal products.

L-3 | Case study - Spinosave®: A point-of-care TEP strategy for acute spinal cord injury

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Acute traumatic spinal cord injury (SCI) is currently managed through decompression, stabilization, and supportive care, while no established regenerative therapy is available to effectively modulate secondary degeneration and promote tissue repair. In this context, cell-based regenerative approaches have attracted growing interest, although their therapeutic efficacy is often limited by poor cell survival and persistence at the injury site. Biomaterial-based delivery systems have therefore emerged as supportive strategies to improve local cell retention and regenerative activity.

To address these challenges, Regenera developed SpinoSave®, a point-of-care Tissue Engineered Product (TEP) combining autologous stromal vascular fraction (SVF) with a biomimetic hydrogel platform designed for localized epidural delivery during acute SCI surgery. The proprietary chemically crosslinked hydrogel was optimized to reproduce key physicochemical and structural features commonly associated with ECM-inspired systems, while improving homogeneous cell distribution, nutrient diffusion, and controlled biodegradation, thereby promoting SVF viability and persistence within the matrix. In addition, particular attention was dedicated to process standardization and industrial translation, including modular hydrogel configuration, terminal sterilization compatibility, and scalable manufacturing strategies.

The therapeutic rationale relies on the multimodal paracrine activity of SVF, including immunomodulatory, angiogenic, neuroprotective, and matrix-remodeling effects, while the proposed intraoperative workflow integrates adipose tissue harvesting, bedside SVF isolation, hydrogel loading, and localized epidural implantation during decompression/stabilization surgery, thereby enabling a rapid point-of-care therapeutic approach without ex vivo cell expansion.

Preclinical studies demonstrated sustained SVF viability within the hydrogel matrix together with encouraging functional recovery signals in rodent SCI models. In parallel, the platform has already received important regulatory recognition, including EMA classification as a Tissue Engineered Product (TEP) and Orphan Drug Designation (ODD), while the hydrogel component was classified as an excipient within the TEP framework.

Overall, SpinoSave® represents a translational regenerative strategy integrating biomaterial-assisted cell delivery, point-of-care therapy, and regulatory-oriented development toward future advanced therapeutic approaches for SCI.

L-4 From bench to bedside: Navigating the challenges of ATMP manufacturing in an academic GMP facility

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Advanced Therapy Medicinal Products (ATMPs), encompassing gene therapies, somatic cell therapies, and tissue-engineered products, represent a class of biopharmaceuticals with significant potential for treating previously intractable diseases. Unlike conventional pharmaceuticals, ATMPs are often produced in small batches tailored to individual patients or small patient cohorts, making academic and hospital-based manufacturing facilities (so-called "academic GMP facilities") increasingly relevant players in their production, particularly during early-phase clinical development.

Manufacturing ATMPs within an academic setting presents unique challenges and opportunities. On one hand, academic facilities benefit from proximity to research expertise, clinical infrastructure, and patient populations, enabling rapid translation from bench to bedside and facilitating investigator-initiated trials. On the other hand, these facilities must navigate stringent Good Manufacturing Practice (GMP) requirements, regulatory compliance, quality control, and quality assurance frameworks typically associated with industrial-scale production, despite operating with more limited resources, staffing, and throughput capacity.

Key considerations for academic ATMP manufacturing include facility design and cleanroom classification, closed and automated processing systems to minimize contamination risk, robust supply chain management for critical raw materials (such as viral vectors and cell sources), personnel training, and the establishment of quality management systems compliant with national and international regulations.

This lesson discusses the operational, regulatory, and economic challenges faced by academic institutions engaged in ATMP manufacturing, highlighting strategies to ensure product quality, patient safety, and regulatory compliance while maintaining the flexibility and innovation-driven culture characteristic of academic research environments. Concrete examples of ATMP development will be presented to illustrate how these challenges are addressed in practice. Ultimately, strengthening academic manufacturing capacity is essential to accelerating the clinical translation of cell and gene therapies and expanding patient access to these advanced

L-5 | Additive manufacturing technologies for tissue engineering

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Additive manufacturing technologies, more commonly known as 3D printing, have become increasingly widespread in the clinical field for a broad range of applications, from the production of patient-specific anatomical models for pre-operative planning and surgical simulation to the fabrication of innovative prostheses and medical devices. Additive manufacturing is widely regarded as an enabling technology, as it can overcome many of the geometrical limitations of conventional manufacturing methods and produce complex shapes that would be difficult or impossible to obtain otherwise. In addition, several additive manufacturing technologies allow the combination of multiple materials and the local tuning of material properties.

Additive manufacturing encompasses a highly heterogeneous group of technologies and materials, enabling the processing of metals, ceramics, polymers, and fiber-reinforced materials, including biocompatible and implantable materials. In this context, the combination of material properties and the geometrical freedom offered by additive manufacturing plays a key role in tissue engineering applications, paving the way for the fine tuning of the biomechanical and biological properties of tissue substitutes tailored to specific patient needs.

The lesson will introduce the most widely used additive manufacturing techniques in the field of tissue engineering and will focus in particular on thermoplastic-based technologies for the tuning of biomechanical properties.

L-6 | Tendon disorders: Clinical pathways, unmet needs, and emerging regenerative perspectives

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Tendon disorders are a major source of pain, mobility loss, and long-term disability in physiatric practice. Their impact on gait, balance, and participation is substantial, and the combination of poor vascularization, slow healing, and high mechanical demand makes tendons particularly challenging to treat. This presentation aims to outline the clinical rationale for improving current care pathways and to highlight how regenerative and minimally invasive approaches may address persistent gaps in tendon healing.

Tendons have a hierarchical structure in which collagen organization, extracellular matrix composition, and mechanobiology play essential roles in load transmission and functional recovery. Clinically, tendon disorders range from chronic tendinopathies characterized by degeneration and failed healing to acute ruptures that cause immediate functional deficits. Risk factors include biomechanical overload, metabolic conditions, and neurological disorders such as multiple sclerosis, where altered motor patterns and spasticity increase vulnerability. Diagnosis relies on clinical examination, imaging, and functional assessment.

Standard care progresses from first-line conservative management, including load modulation, therapeutic exercise, and interdisciplinary rehabilitation, to second-line options such as shockwave therapy, injections, and orthoses. When these fail, surgical repair or minimally invasive procedures are considered, followed by demanding rehabilitation. Despite these strategies, many patients experience incomplete healing, persistent weakness, tendon stiffness, or proprioceptive deficits. Achilles tendon rupture exemplifies these challenges, with complex decision-making and frequent rehabilitation pitfalls.

These limitations underscore the need for solutions that support early loading, improve tissue quality, and reduce immobilization, especially in vulnerable populations such as older adults or individuals with neurological conditions. Regenerative biomaterials and imaging-guided minimally invasive techniques represent promising directions. From a clinician's perspective, the TEN4CARE injectable 4D nanocomposite fibrous hydrogel may offer a meaningful advance by enhancing structural support, promoting more effective healing, and facilitating earlier functional recovery. Its integration into rehabilitation pathways could improve long-term outcomes and address unmet clinical needs.

L-7 | Bridging science and society in bio-nanotechnology: The TEN4CARE journey

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Advances in bio-nanotechnology increasingly require the integration of Social Sciences and Humanities (SSH) to ensure that new materials and devices respond to real human needs and are trusted by those who will ultimately use them. Within this perspective, involving patients and citizens as active contributors rather than passive recipients becomes essential for responsible and socially relevant innovation. This work aims to illustrate how structured Public and Patient Involvement and Engagement can be embedded in the early development of an innovative 4D hydrogel scaffold for tendon repair, using the European TEN4CARE project as a case study.

The approach is based on a multi-actor model that combines the professional expertise of clinicians with the lived experience of people with Multiple Sclerosis, many of whom experience tendinopathies. Methods include mapping engagement levels from basic information to active co-creation, analysing the contribution of patient organizations as trusted intermediaries, and reviewing existing infrastructures, tools and guidelines. Practical aspects such as feasibility, time, budget, and ethical considerations are examined to identify enabling factors and barriers for meaningful participation. Preliminary results from the TEN4CARE experience show that early dialogue with patients and clinicians helps refine research questions, anticipate usability issues, and align technical development with real-world rehabilitation needs. Interactive polling and live surveys are used to make students experience Public and Patient Involvement and Engagement firsthand, enabling a shift from theoretical understanding to direct participatory practice during the session.

Embedding participatory practices in biomaterial development and pre-clinical research strengthens the relevance, acceptability, and future adoption of technological innovations. This approach supports more responsible research trajectories and contributes to building long-term trust between science and society, suggesting that structured involvement should become a standard component of pre-clinical research pathways.

Overall, thermoplastic biomaterials offer an exciting bridge between materials science and biomedicine, paving the way toward innovative and customizable regenerative therapies.

L-8 | Thermoplastic biomaterials for tissue engineering and regeneration

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Thermoplastic biomaterials are rapidly gaining attention as versatile platforms in tissue engineering and regenerative medicine, thanks to their processability, tunable properties, and capacity for structural customization. Unlike thermosetting systems, thermoplastics can be reshaped and reprocessed, offering unique opportunities to design tissue engineering platforms with controlled architectures and mechanical properties that closely resemble those of native tissues, an essential requirement for successful regeneration.

In this field, scaffolds must be carefully engineered, as they provide a temporary extracellular matrix (ECM)-like environment that supports cell adhesion, proliferation, and differentiation, ultimately guiding new tissue formation. The selection of suitable biomaterials is therefore critical and requires a balance between biocompatibility, biodegradability, processability, and mechanical performance.

Among thermoplastic systems, elastomers, and shape-memory polymers are particularly promising. Thermoplastic elastomers combine strength and flexibility through their unique microstructure, enabling large and reversible deformations. Shape-memory thermoplastics further enhance functionality by recovering a predefined shape in response to external stimuli, such as temperature, paving the way to minimally invasive implantation and dynamic adaptation in vivo.

This lecture will introduce the fundamental concepts of thermoplastic biomaterials and explore their use in the design of tissue regeneration platforms, including scaffolds and hydrogel systems. Particular attention will be given to how these materials can be engineered to support cell encapsulation, tissue growth, and controlled drug release. In addition, their intrinsic processability makes thermoplastics highly suitable for advanced manufacturing techniques such as 3D printing, enabling the fabrication of patient-specific constructs with precise architectures.

L-9 | Understanding burn injury responses: Lessons from porcine models and emerging human-based systems

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Burn wounds are highly dynamic injuries: within hours, damaged tissue, inflammation, metabolic stress, and repair processes begin to interact and shape the outcome of healing. Understanding these local responses is essential for improving burn treatment, but it also requires models that reflect the complexity of human skin.
A time-resolved porcine burn wound model will be presented which was designed to follow local tissue responses from the early injury phase through regeneration. Using histology, gene expression, metabolic profiling, inflammatory mediator analysis, and comparison with human burn tissue, we observed how burn wounds progress from necrosis and acute inflammation toward re-epithelialization and dermal repair. The model captured several key features also seen in human burn wounds, including inflammatory activation and broad metabolic remodeling. At the same time, differences in hypoxia signaling and tissue remodeling highlighted the limitations of translating animal data directly to the human situation.
Beyond discussing what this model can teach about burn wound healing, the talk will also address where the field may be heading. Human ex vivo burn wound models and advanced in vitro systems, including reconstructed skin, organ-on-chip approaches, and immune-competent models, offer promising opportunities to study burn injury in a more human-relevant way. In the long term, these approaches may help reduce the need for animal experiments while improving the predictability of preclinical burn research.

L-10 | Nanomedicine for tissue regeneration: Nanoparticles as tools and carriers

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Tissue regeneration presents persistent clinical challenges rooted in the complexity of the wound microenvironment, the limitations of conventional therapies, and the spatiotemporal precision required for effective repair. Nanomedicine has emerged as a compelling approach to address these needs, offering tools that can interact with biological systems at the scale where healing actually happens.

This lecture provides an overview of how nanoparticles contribute to tissue regeneration, both as bioactive agents in their own right and as delivery vehicles for therapeutic molecules. We will explore the major nanoparticle classes relevant to regenerative medicine, from polymeric and lipid-based systems to inorganic nanomaterials, and discuss how their properties can be tailored to specific tissue contexts including cardiac and intervertebral disc repair.

Particular attention will be given to nanoparticle-mediated delivery of nucleic acid therapeutics illustrating how nanocarriers can unlock the therapeutic potential of molecules that would otherwise face significant biological barriers. We will also touch on stimuli-responsive systems and their growing role in combining structural support with on-demand therapeutic release.

The lecture will close with a look at where the field stands today, what has been achieved in preclinical models, where the translational gaps remain, and what the most promising directions look like going forward.

L-11 | Next generation medical devices: translational approach

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Tendon and ligament injuries account for roughly half of the 33 million musculoskeletal injuries reported annually worldwide, and current surgical treatments remain invasive, with prolonged rehabilitation and risk of recurrence. We hypothesized that a physicochemically characterized 4D nanocomposite fibrous hydrogel, developed within the Horizon Europe project TEN4CARE, could progress toward clinical translation by combining functional performance with biocompatibility assessment aligned with ISO 10993, the international standard for the biological evaluation of medical devices. These injectable hydrogel, co-loaded with magnetic nanoparticles and an anti-inflammatory drug, is characterized by medical device industry accepted methodologies (e.g., visual and imaging techniques, rheology and viscosimetry, tensile strength, chemical compositions and others). Biocompatibility is evaluated following ISO 10993 guidance, including cytotoxicity, sensitization, and irritation testing, alongside degradation and extractables analysis, to anticipate biological risk ahead of preclinical studies. Subsequently, new alternative methodologies (NAMS) are to investigate release kinetics consistent with in vitro data, electromagnetically triggered mechanical reinforcement at the injury site, and favourable tissue integration without any adverse local or systemic response. These findings are to be compared to a small in vivo campaign to demonstrate that integrating physicochemical characterization with ISO 10993-compliant biocompatibility testing strengthens the preclinical evidence base and supports a regulatory roadmap for clinical translation of next-generation tendon-repair devices.

L-12 | Automation in pharmaceutical manufacturing: perspective and trends

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Engineering has always been part of medicine, from simple medical tools to imaging systems, rehabilitation devices, automated laboratories, and advanced manufacturing platforms. Today, medical technologies are moving toward more automated and robotic solutions, especially in pharmaceutical, biomedical, and tissue engineering applications where precision, repeatability, safety, and contamination control are essential. The aim of this lecture is to show how engineering has progressively changed medicine and to discuss how automation can support future biomedical manufacturing while still requiring trust, validation, and human supervision. The lecture follows a visual and application-based path. It first gives a short historical overview of how engineering entered medicine and how many devices used today in biomedical laboratories are the result of progressive technological development. It then presents examples of modern medical and biomedical technologies, including rehabilitation systems, surgical robots, automated laboratory platforms, hospital logistics robots, three-dimensional printing systems, and manufacturing robots. Their benefits are discussed together with important concerns, such as human error, process variability, safety, responsibility, and the need to prove that automated systems are reliable and controllable. As practical examples, ongoing research activities at the University of Pavia are presented as short case studies, including robotic automation for controlled pharmaceutical environments, robotic liquid handling, and human–robot interaction. The lecture highlights that the future of biomedical manufacturing is not about replacing humans, but about building trustworthy systems that can support clinicians, researchers, and operators. These systems can improve reproducibility, reduce risk, and make advanced medical manufacturing safer, more accessible, and more reliable.

L-13 | What's next: The use of knowledge in research

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Research and innovation activities generate multiple technical and scientific results, data, prototypes and potential scalable processes and products. All these outcomes and knowledge produced will not generate any value (scientific, economical, societal) if they are not properly used. Use of knowledge can include communication, dissemination, generation of IP, exploitation: all of them should be understood as interconnected, not scattered options, as they must be considered in the adequate time framework (e.g. early disclosure of results can impair the obtaining of patents). During these lessons we will address all these aspects related to the use of knowledge, highlighting strategies for communication and dissemination and with a special emphasis on IP protection (patenting, trade secrets, etc). and exploitation avenues for scientific results.

L-14 | Electrospinning as a powerful tool for tissue engineering applications

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Electrospinning is a versatile and widely adopted technique for the fabrication of continuous micro- and nanofibrous membranes through the application of a high-voltage electric field. In this process, a polymer solution is extruded from a spinneret and subjected to electrostatic forces that overcome surface tension, forming a charged jet. As the jet travels toward a grounded collector, it undergoes elongation and solvent evaporation, resulting in the deposition of solid fibers with diameters ranging from the micrometer to the nanometer scale. Key process parameters, including solution viscosity, surface tension, applied voltage, flow rate, collector geometry and distance from the spinneret, critically influence fiber morphology, alignment, and porosity.

From a tissue engineering perspective, electrospinning is particularly attractive due to its ability to mimic the structural features of the extracellular matrix, providing high surface area-to-volume ratios and tunable mechanical properties. Electrospun scaffolds can support cell adhesion, proliferation, and differentiation, making them suitable for regenerating a variety of tissues such as skin and musculoskeletal systems (*e.g.,* tendons and ligaments). A notable advantage of electrospinning lies in its versatility in material selection and processing. Both natural and synthetic polymers can be employed, as well as their blends and composites, enabling precise control over biological and mechanical performance. Importantly, the technique can be applied to sustainable, bio-based materials derived from food industry by-products, such as gelatin and keratin (*e.g.,* to fabricate skin models). Beyond simple scaffolds, electrospinning enables the creation of complex *in vitro* models, including electrospun membranes that simulate physiological barriers (*e.g.,* membranes that replicate the blood–retinal barrier, intestinal barrier models for studying microbiota-gut interaction, stretchable membranes that mimic the dynamic environment of the alveolar barrier).

Ultimately, electrospinning represents a powerful biomedical tool, enabling the development of physiologically relevant models and advanced scaffolds that can improve disease modeling, drug screening, and regenerative medicine strategies.

L-15 | Regulatory of medical devices

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For decades, medical devices (MDs) and in vitro diagnostic medical devices (IVDs) placed on the European market were regulated under three Directives: the Active Implantable Medical Devices Directive (90/385/EEC), the Medical Devices Directive (93/42/EEC, MDD), and the In Vitro Diagnostic Medical Devices Directive (98/79/EC, IVDD). This framework, based on minimal harmonisation, relied on manufacturer self-assessment and on Notified Bodies whose scrutiny varied considerably across Member States. High-profile safety incidents, most notably the PIP breast implant scandal, exposed structural weaknesses in traceability, clinical evidence requirements and post-market surveillance, prompting a full legislative overhaul.

In 2017, the European Union adopted two Regulations, directly applicable in all Member States without national transposition: Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR). Compared with the
former Directives, both Regulations introduce stricter requirements for clinical evidence and performance evaluation, an expanded scope covering products without an intended medical purpose, a risk-based classification system (notably a substantial reclassification of most IVDs, previously largely self-certified), reinforced obligations for economic operators, mandatory Unique Device Identification (UDI) for traceability, and a centralised European database (EUDAMED).

The transition from Directives to Regulations has been gradual and, due to Notified Body capacity constraints, repeatedly extended through corrigenda and amending Regulations, resulting in staggered deadlines depending on device risk class and certificate status. The lecture will also outline how conformity assessment and certification work in Europe: manufacturers self-certify low-risk devices, while higher-risk devices require the involvement of a Notified Body, designated and audited by national Competent Authorities and the European Commission, to assess the technical documentation and quality management system before CE marking can be affixed and the device placed on the market. The ultimate goal is to give a compressive overview of the European certification system of medical devices and IVDs.