



Empowering Innovation in Life Sciences:

*Comprehensive Services for Medical Technology,
Biotechnology, and Healthcare Industries Worldwide*

leap:up GmbH - The Life Science Enabler

leap:up GmbH (formerly biosaxony Management GmbH) empowers founders, startups, and SMEs in the life sciences to take significant steps towards innovation, market entry, commercialization, and growth.

Our vision:

A sustainably healthier world.

Our mission is to support scientists, companies and startups in the field of life sciences to transform their innovative ideas into scalable business models. Through our projects and world-class services, we help to bridge the gap between idea and realization.



“leap:up” stands for bold leaps into the future of life sciences. As a life science enabler, we create optimal conditions for the realization of groundbreaking ideas.

Our portfolio includes acceleration and development services for life science projects, regulatory support, training programs, and events through our in-house academy, as well as the provision of state-of-the-art co-working labs in Leipzig. We are actively expanding our international presence and service, including investor relations and funding opportunities.

Our focus areas include diagnostics, cell and gene therapy, radiopharmacy, smart medical devices, robotics and AI, digital health, and phage therapy.



TABLE OF CONTENTS:



3D-PRINTING

6



ACADEMY

8



BACK OFFICE MANAGEMENT

10



CONSULTING

12



MARKETING & EVENTS

14



NETWORKING

16



PRODUCT DEVELOPMENT

18



PUBLIC AFFAIRS

20



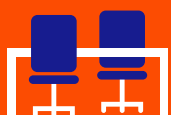
REGULATORY AFFAIRS

22



WORKING GROUPS

24



COWORKING LAB

26



CLINICAL COOPERATION

28



INVESTOR RELATIONS

30



3D-PRINTING

Streamlining Your Health Innovations

3D-Prototyping

Our 3D-prototyping solutions help streamline your health innovations by reducing costs and risks for accelerating time-to-market. Whether you are creating a design, personalizing a product, or testing and refining your tools and models, we are here to assist you every step of the way.

How We Support Your Success

3D-Printing / Rapid Prototyping

Are you developing medical devices, customized orthoses or anatomical models? Or innovating in the fields of biotech, diagnostics or drug delivery? Our rapid prototyping technology (e.g. HP JetFusion, Formlabs SLA) help you test, evaluate and refine your designs before deciding on your next steps.

3D-Printing / Small Batches

You only need a limited amount of high-quality prototypes and/or customized solutions tailored to specific requirements (e.g. biocompatible, sterilizable)? We support your small-batch manufacturing needs with the HP Jet Fusion 3D technology which offers fast, precise, and scalable 3D-printing.

Component Analysis

During product development, your final prototype needs to align closely with the manufacturing specifications or regulatory requirements. Our component analysis tools (e.g. 3D-scan, CT/micro-CT) help you identify problems early and troubleshoot efficiently so you save time and resources.



Component Design / Consulting

Our suite of component design tools and know-how (e.g. CAE/ CAD) help you optimize and accelerate the prototyping process. The result: Functional, safe, reliable, and patient-specific products which can give your company the competitive edge it needs to succeed.

Further, we also advise you on regulatory requirements for 3D printed products, with regard to medical device approval according to MDR (EU 2017/745).

Some of these services are provided through partnership programs.

info@leap-up.com





ACADEMY

Providing Prime Learning Experiences

Training & Education

Our expert-led training and continuing education programs are tailored to meet the demands of today's dynamic job market. By modelling and supporting lifelong learning, they help you access and retain a motivated workforce – an essential cornerstone for your success.

How We Support Your Success

Training GMP Operators

In a three-month practice-oriented training course, we upskill industry outsiders as GMP operators for cell and gene therapy labs. Our members can thus quickly and flexibly access qualified personnel with the skills and knowledge needed to support a growing enterprise.

Life Sciences Workshops

Our life sciences workshops focus on the fields of biotechnology, pharmaceuticals, and healthcare. Participants leave with the enhanced skills, specialized knowledge and deeper insights they need to navigate the industry and advance their careers.

Soft Skills Workshops

In an increasingly global and collaborative work environment, soft skills are essential to succeed. Our workshops cover topics such as time- and self-management, leadership and negotiation, conflict management and resolution, as well as intercultural skills.



Business Skills Workshops

You want to empower your teams to excel in a dynamic business environment? Our experienced trainers get them up to speed on classic and agile project management, contract law, drafting of cooperation agreements, and on the secrets of successful business development.

Some of these services are provided through partnership programs.

academy@leap-up.com
qualibiopharma@leap-up.com





BACK OFFICE MANAGEMENT

Focus On Essentials

Back Office Services

Our portfolio of back office management services gives you the freedom to focus on your core business. Instead of secondary support tasks, you can concentrate on things that matter – for example growth, innovation, and customer satisfaction.

How We Support Your Success

Accounting Services

Too busy with your business to stay abreast of critical financial tasks? We've got you covered! Our team of experts can support you with a wide range of specialized accounting services, including preparatory bookkeeping, financial reporting, and tax compliance.

Human Resources

Whether you are looking for assistance with staffing, understanding the intricacies of German labor laws, or any other HR issues – we will find support for you!

Postal Solutions

For the transition period before your company moves to Leipzig, we offer the option of operating your mailbox at our centrally located BIO CITY Innovation Center. You can either collect your own letters and packages or have our friendly service team forward your mail to a secondary location of your choice.



***Connect to
Funding Experts***

Navigating the European and/or German funding landscape can pose a challenge at the best of times. Our experts can help you with everything from preparing project reports, to issuing calls for funds, to providing proof-of-use documentation – just get in touch!

***Specialist for
Health and Safety***

By law, companies located in Germany have to appoint a person for health and safety. Health and Safety regulations based on a risk assessment are essential to maintaining a safe working environment and protecting your staff and company's assets. In cooperation with external partners, we provide the contractual framework in which you can easily opt in (and out) to fulfill this requirement - for extra peace of mind.

backoffice@leap-up.com





CONSULTING

Expert Guidance On The Path To Growth

Navigating Markets

Whether you are a biotech, medtech (including IvD) or other life science-related company – our expert guidance helps you competently navigate Germany's healthcare landscape, increase operational efficiency, and put you on the path to scalable growth.

How We Support Your Success

Market Analysis

Understanding your market(s) is key for your success. From collecting relevant data to giving strategic recommendations – and everything in between – our team has the experience and expertise to assist you on your journey.

Project Management

You've set the goals, timelines, and budget for your project—but now you realize you need extra support? Our project managers have all the tools and know-how needed to help you manage resources, coordinate your teams, and track progress to a successful outcome.

Funding / Financing

Looking for someone who can advise you on how to identify and secure funding in Europe and/or Germany? Our experienced consultants help you navigate funding options and prepare compelling proposals, all while ensuring compliance with existing financial regulations.



Partnership Brokering

Whether you're seeking a reliable service provider, an experienced clinical partner, or support with technology transfer, we're your first point of contact. Our team has access to a broad and growing network of potential partners, and we'd be happy to connect you with them.

Support Services

Want to establish a company or subsidiary in Europe and/or Germany? Or are you developing a product or medical device you'd like to launch in these markets? Our team can support you with a range of services, including navigating Europe's regulatory and reimbursement landscape.

info@leap-up.com





MARKETING & EVENTS

Visibility For Your Company

Audience Outreach

Effective marketing helps communicate the value of your products and services, as well as building your credibility and reputation. We have the necessary tools and resources to make sure that your messages reach the right audiences at the right time – for maximum impact.

How We Support Your Success

Lead Generation

Generating qualified leads to drive business growth is an ongoing challenge for every company. Since we are present at relevant life science conventions such as BIO International and BIO-Europe, our members get direct access to potential customers, partners, and industry professionals.

Marketing Communications

Healthcare is a trust-driven market that is built on consistent, long-term interactions. Our team can help you identify and implement the marketing communications measures you need to succeed – whether through direct mailings, social media posts (e.g. LinkedIn) or newsletters.

Workshops / Presentations

We organize external workshops and presentations designed to inspire innovation and foster growth. Members can access our extensive network of industry experts and key opinion leaders, supported by our science-savvy team with cross-cultural marketing skills.



Talent Acquisition

Our members can take advantage of our online job posting platform to attract top talent in the life science industry. For a small fee, we facilitate the perfect match for both job seekers and hiring managers.

Events

When we attend life science events, we invite our members to participate. Your logo can appear on materials such as invitations, place cards, light boxes, flyers, posters, and strategically placed ad banners. Members also enjoy a set number of complimentary tickets for every event.

marketing@leap-up.com

events@leap-up.com





NETWORKING

Connecting People And Ideas

Access / Support

In a dynamic and global market, connecting with the right people can be crucial to your company's success. Whether at one of our get-togethers or through conferences, trade fairs and partnering meetings – our networking forums help you connect with relevant stakeholders for your business.

How We Support Your Success

Market Entry

Breaking into new markets can be challenging. We offer strategic networking opportunities with partners from industry, the scientific community, and government. This targeted approach can help you build robust partnerships to share knowledge and achieve mutual goals.

International Contacts

In more than 20 years, we have built our network outwards from Germany to include Europe and many parts of the world. Our members benefit from the valuable expertise and fresh perspectives they gain after interacting and/or partnering with this global collective.

Project Partners

Launching a project brings its own set of hurdles: Where do I find a partner who is an expert on this specific topic? Who can connect me with hidden talent? This is where we come in – our network of contacts is an invaluable resource for getting your project(s) off the ground.



Technology Access

If you want to tackle a specific challenge and/or innovate faster, you sometimes need to look outside your own field. Across our life science cluster, we can help connect you with other technologies such as AI/ML, IT/data science or engineering/robotics – to name just a few.

Higher Visibility

You may have a range of clinical, technology and/or business partners who can benefit from achieving higher visibility on the global stage. We can help by representing them at national and international trade fairs, conferences and partnering events.

info@leap-up.com





PRODUCT DEVELOPMENT

Shaping Future Products and Services

Development / UX Testing

Creating health-related products and services brings its own set of challenges, from stringent regulatory requirements to high user expectations. Our development and UX testing experts usher you competently through this demanding phase on the path to market success.

How We Support Your Success

Innovation Workshops

Looking for fresh input or a sparring partner to bounce your own ideas off? Our innovation workshops can be the first step in developing new solutions – or in refining existing ones. Led by experienced facilitators, these sessions foster creativity by bringing together cross-functional teams and key stakeholders. Participants can explore unmet needs, prototype ideas and brainstorm innovative solutions. The goal: To send you home with an actionable roadmap for your future success.

User Workshops

When it comes to healthcare-related products, usability testing is a critical step in the development process. We have many years of experience in implementing workshops for potential users. Before identifying your key users, we will clarify your objectives and gain a full understanding of your product. Then our experts will tailor one or more workshops to gather feedback, observe user interactions, and gain insights into potential pain points regarding your product or service. This method fosters a user-centric design and ensures that your solutions align with real-world user experiences.



info@leap-up.com





PUBLIC AFFAIRS

Building Strong Relationships

Advocacy / Dialogue

In today's global and interconnected business environment, establishing trust is essential for your company to thrive. Our public affairs experts help you build and foster strong relationships with policy makers, regulatory bodies, media representatives and the general public.

How We Support Your Success

Political and Social Advocacy

Whether you are establishing a company or launching a new product, navigating the policy landscape in Germany and/or Europe can be daunting. As we are in constant dialogue with key decision-makers at the state and federal levels, our public affairs experts are always abreast of recent policy developments. Our experienced team will stay by your side to help address potential legislative hurdles and advocate for regulatory pathways that support innovation. We can also help you build strong relationships with relevant media outlets to foster reputation-building and establish long-term trust.

Expert Consulting

Building and maintaining a thriving ecosystem in a complex industry like the life sciences is challenging. That's why we offer expert consulting services tailored specifically for policymakers and administrators. Backed by many years of experience, our team has developed a deep understanding of this sector and how it works. We are happy to share our in-depth knowledge and strategic insights with you, including on topics such as regulatory frameworks, funding programs and public-private partnerships.



Committee Representation

We regularly participate in committees and/or panels on a regional and national level to stay up-to-date on any issues that might impact our members. This participation allows us to ensure that our members' perspectives are heard – and to voice any concerns that might arise. Gaining early insights into ongoing developments also allows us to prepare and strategize in ways that best serve our clients. Last but not least, our presence on these panels reinforces our strong network by putting us in direct contact with decision-makers and other stakeholders – which ultimately benefits our members and advances their goals.

info@leap-up.com





REGULATORY AFFAIRS

Ensuring Quality and Compliance

Consulting / Services

Are you tired of dealing with Europe's complex and constantly evolving regulations? We're here to help! Whether you offer medical devices or *in vitro* diagnostic medical devices, our regulatory consulting and services help you get them to market, with confidence – and within the law.

How We Support Your Success

(QM) Quality Management

We offer our members ongoing operative QM support and training to help their companies to achieve and sustain consistently high standards. Our goal is to ensure compliance with current regulatory requirements in Germany and Europe.



MDR / IVDR

Members who have to deal with the EU Medical Devices Regulation (MDR) and/or In Vitro Diagnostic Regulation (IVDR) can rely on guidance from our experienced consultants. We also offer support in reviewing and preparing technical documentation in accordance with MDR 745/2017 and IVDR 746/2017.

ISO 13485

We support you in building a DIN EN ISO 13485-compliant Quality Management System by analyzing your current processes, identifying gaps, and designing a tailored implementation strategy. Our services include creating necessary documentation, such as the Quality Manual and procedures, and conducting employee training to ensure alignment with the standard. Finally, we assist with internal audits and prepare your organization for successful certification.

Our teams offer members general ISO 13485 consulting for improved quality – as well as carrying out internal audits within the framework of ISO 13485:2021.

Responsible Persons

We also provide our members with an external QMO (Quality Management Officer) or Person Responsible for Regulatory Compliance (PRRC), if needed. If you are a non-EU medical device manufacturer, we can also provide a European Community Representative (EC-REP, EU-REP).

Comprehensive Regulatory Advice

Beyond these specialized topics, our consulting team offers comprehensive support on a broad range of regulatory topics. This includes expertise in risk management, clinical evaluation, usability, software lifecycles and post-market surveillance, ensuring your company is fully equipped to meet all relevant regulatory challenges.

regulatory@leap-up.com





WORKING GROUPS

Fostering Collaboration for Common Goals

Networks

Sitting alone in your lab or office won't always help you find solutions to knotty problems. That's why we foster collaboration by supporting a variety of different working groups. Feel free to join and network with colleagues and experts who may have that insight you've been looking for!

How We Support Your Success

Life Sciences Regular's table

This group meets quarterly at a venue in Leipzig and includes members from the corporate and academic worlds. Meetings run for about an hour and cover current life science-related topics and associated funding opportunities, followed by informal networking over snacks and drinks.

Biotech Hub Strategy

This working group meets 1-2 times a year and includes representatives from municipalities and ministries, as well as the Saxony Economic Development Corporation. Its focus is on Saxony's biotech strategy, including topics such as regional marketing and development or potential solutions to the skilled-labor shortage.

Sterile Technology

This group meets 2-3 times a year, hosted in turn by different members. Its goal is to foster open discussions on technically relevant topics in the field of sterilization and related issues such as e-beam, medical device sterilization, logistics or the sterilization of polymers.



Radiopharmacy

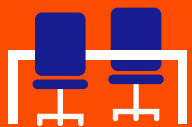
A dynamic network of experts has formed around Saxony's radiopharmacy cluster nukliD®, committed to advancing the sector in this part of Germany. The cluster's members are working on pioneering solutions which are opening up new perspectives for the treatment of cancer.

Good Manufacturing Practice (GMP)

This network is currently being established and aims to give members the opportunity to share their experiences and solve ongoing challenges. Topics might focus on issues such as regulatory compliance, quality assurance, risk management, and process optimization.

info@leap-up.com





COWORKING LAB

Flexible Spaces For High Productivity

Infrastructure

Looking for a flexible space to work, research and meet innovators in the heart of Leipzig? Our co-working solutions at BIO CITY Leipzig are abuzz with trailblazing and growing companies. Come join them and take advantage of the networks and infrastructure we have built to support you!

How We Support Your Success

Office Spaces

Whether your teams are working in-house or remotely, our versatile office spaces can be scaled up or down to meet your needs. Climate-controlled rooms with ergonomic furniture and high-speed internet offer a comfortable working environment with seamless connectivity. Your employees benefit from our cafeteria, underground parking garage and on-site security staff. And if you want to meet fellow innovators, do join one of our numerous free networking events!

Laboratory Spaces

Members can use our laboratory spaces (S1/S2 standard) for their research and development. We have S1 genetic engineering and biochemical wet labs, as well as a 3D printing lab and an electronics lab for prototyping. You can take advantage of our lab supply services which offer special discounts on lab chemicals; we also offer chemical disposal services. Last but not least: Enjoy our free WiFi as well as our on-site printer and scanner.



Electronic Workstations

Our CoWorking Lab is fitted with a range of electronic workstations for your researchers, engineers and technicians to utilize. Equipped with state-of-the-art technology, they allow you to streamline complex workflows without having to make any costly upfront investments. Your teams can perform tasks like designing, testing and prototyping in the immediate vicinity of your lab(s) – and without having to leave the building.

Conference Rooms

Our light-filled atrium at BIO CITY Leipzig is a meeting room in itself, but we also offer our members 'bona fide' conference rooms in varying sizes. They are equipped with modern audio-visual systems which allow you to add remote participants to any team discussion. Need a flipchart, whiteboard or extra catering? Our service team is happy to provide whatever you need to make your meeting a success. And if you are a member, we'll give you a special discount on larger conference rooms too!

medicalforge@leap-up.com





CLINICAL COOPERATION

Collaboration for Optimal Results

Partnerships / Know-How

Collaboration between industry, academia and healthcare providers is key when working on medical solutions that address real-world healthcare challenges. We help you access the experts and clinics you need to develop and improve your products – and ensure that they perform well in the long term.

How We Support Your Success

Curated Matchmaking

Looking for clinical partners? At leap:up, we specialize in fostering seamless connections between innovative medical technology companies and clinical partners. Our curated matchmaking service ensures that you find the ideal clinical collaborators who align with your project goals and therapeutic areas. Our network of clinics is active in a broad range of medical fields and can support you with everything from performing clinical trials to implementing real-world testing.

Project Support

Our team has the expertise and resources needed to ensure that your clinical projects run smoothly. We support everything from pre-project planning to post-project support. Unsure about compliance issues? We make sure your projects meet all current legal, ethical, and regulatory standards. Get in touch if you want to minimize hassle and maximize the speed with which your products get to market.

Product Optimization

Healthcare professionals and patients who use innovations in real-world settings have unique insights into those products' strengths and limitations. That's why we support our clients in obtaining clinical feedback to optimize their products. Our team can set up and analyze usability tests, surveys, interviews, or other observational studies for your product. Based on the data gathered, you can then refine and optimize your innovations to ensure robust performance that will improve patient outcomes.



Operations Management

If you collaborate with one of our clinics, you may need to lease specialized medical equipment to reach your goals. Our team can support you every step of the way: From assessing your needs, researching good vendors and negotiating contracts – to ensuring delivery and installation, monitoring performance, and evaluating the outcomes based on your specific targets. Let us customize the perfect solution for you!



medicalforge@leap-up.com





INVESTOR RELATIONS

Showcasing Your Value And Potential

Financing

We get it – finding funding can be daunting. So, feel free to take advantage of our specialized knowledge and contacts to showcase your value and potential to the world of finance. Our customized services can help you build a solid foundation for long-term success.

How We Support Your Success

Tailored Workshops

We offer our members individual or group workshops on a variety of investment-related issues. These include topics such as investment readiness and financing instruments (i.e. term sheets, convertible loans etc.). Participants benefit from expert-led discussions in an environment which encourages networking and peer learning. The goal: To empower you with the practical knowledge you need to navigate an ever-changing global investment landscape.



IR Events

Get-togethers are an excellent way of networking with potential investors from around the world. Together with our external partners, we have been organizing finance-related events for many years. These include occasions like an annual Finance Day, the popular Financial Golf Cup and Summer Lounge, as well as informal 'speed-dating' events with investors. Whether you are a spin-off, start-up, or growing company on the rise, you're sure to find an event that can put you in touch with the people you are looking for.

Project-Related Consulting

Our consultants bring a wealth of experience to the table when it comes to finding solutions to our members' financing and investment issues. We will analyze your specific needs to recommend the right funding type, be it venture capital, loans, or alternative financing. We can help you with strategic positioning by identifying your unique market advantages and crafting a compelling narrative around them. By supporting you with professional pitch decks, executive summaries, and financial projections, we help you leave a strong and convincing impression on investors.

Public Relations / Investor Relations

In cooperation with external agency partners, we offer our members a broad range of PR/IR-related services. These include media outreach and relations, crisis communications and management, as well as media monitoring and analysis. We ensure that your IR communications are not just strategy-driven and tailored to meet your individual needs, but also meet any current legal and regulatory requirements. Your success depends on your reputation, so let us help you craft it.

info@leap-up.com



