ProTechTiv

Projects, Technologies & QA Services

COMPANY PROFILE 2026 · EUROPE

Engineering Projects Management and Validation Services

End-to-end engineering management, cleanroom delivery and validation for the pharmaceutical, biopharmaceutical, medical device and medical cannabis industries.



Since 2015 · 21+ years of experience

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OVERVIEW

One Partner From Concept to Hand-Over

ProTechTiv provides engineering projects management, validation and quality assurance services, specializing in the pharmaceutical, medical device and medical cannabis industries. Our mission is to deliver comprehensive, end-to-end solutions that ensure compliance, enhance operational efficiency and drive innovation.

21+	2015	250-500 m^2	3,000 m^2
years in pharma and biopharma	ProTechTiv founded	laboratory spaces	advanced cleanrooms

OUR SERVICES

Engineering Project Management

With more than 21 years of specialized experience in the biopharmaceutical and pharmaceutical industries, we oversee large-scale cleanroom facilities and complex engineering projects from conception to completion. Since ProTechTiv was established in 2015, we have expanded our expertise into the design and management of chemical, microbiological and specialized laboratories, including for the food-tech and medical cannabis sectors.

Our services cover the entire project lifecycle, from the first design and planning of laboratory spaces of 250-500 m^2 to the construction of advanced cleanrooms of up to 3,000 m^2. We manage every phase until final hand-over to the client, with seamless execution in the design, installation and commissioning of process equipment.

As lead integrator, we bridge the gap between R&D and full-scale production, managing URS definition, vendor selection and complex infrastructure (HVAC, HMI, IT). Our approach ensures that even the most intricate projects are completed on time, within budget and to the highest regulatory quality standards.

OUR SERVICES

Validations

We provide a wide range of validation services for both mechanical and computerized systems, ensuring that all equipment and processes meet regulatory requirements and function as intended.

Beyond core system validation, ProTechTiv offers specialized support in documentation gap analysis and remediation plans for cleanroom facilities. We have extensive knowledge in developing and optimizing the full suite of validation documents (URS, FS, IQ, OQ, PQ), ensuring seamless project execution.

Our expertise ensures that your validation documentation and standard operating procedures (SOP) comply with rigorous international standards, including:

Quality System Regulations	**FDA 21 CFR Parts 210, 211 (cGMP)**
Electronic Records and Signatures	**FDA 21 CFR Part 11**
Sterile Manufacturing	**EU Annex 1**
Qualification and Validation	**EU Annex 15**
Cleanroom Classification & Monitoring	**ISO 14644**

We make sure your systems are not only validated, but stay fully ready for regulatory review.

CLEANROOM QUALIFICATION

Cleanroom Qualification & Environmental Monitoring (PQ)

- **End-to-end cleanroom qualification:** full qualification lifecycles (DQ, IQ, OQ, PQ) for pharma and medical device cleanroom facilities, in accordance with ISO 14644 and EU Annex 1.
- **Microbiological sampling & PQ design:** defining, tailoring and executing environmental monitoring (EM) protocols, including viable and non-viable particle sampling, surface sampling and air monitoring during the PQ phase.
- **Audits & regulatory bodies:** hands-on guidance and preparation for inspections and audits by international authorities, including the FDA, Notified Bodies (CE marking) and local Ministries of Health, for full audit readiness and compliant facility hand-over.

CSV

Computerized Systems Validation

Comprehensive validation of computerized systems, with a strong focus on ERP platforms including Priority ERP. We make sure your systems comply with FDA 21 CFR Part 11 and EU Annex 11, and perform reliably and securely throughout their lifecycle.

We specialize in validation planning, risk assessment, requirement traceability, test protocol development and execution, and final reporting, tailored to the pharmaceutical and medical device industries.

SUPPLY CHAIN

Cold Chain & Transport Validation

Validation and qualification services for the pharmaceutical and medical device supply chain. We make sure temperature-sensitive products keep their integrity, safety and quality from the manufacturing site to the end consumer.

Our end-to-end solutions cover every stage of distribution, so your logistics operations are fully compliant with global regulatory expectations.

WHY CHOOSE PROTECHTIV

Our core values set us apart. By integrating our diverse services, clients benefit from our ability to deliver seamless, end-to-end projects. We are committed to being a dependable partner, offering tailored solutions backed by hands-on experience. Our deep understanding of quality and project execution means we have the expertise to take on your most challenging projects.

Creativity	Innovation	Reliability	Responsibility

SOME OF OUR CLIENTS

teva · omrix · api · Liposphere · MediWound · Nanomotion · molex · UroGen Pharma · Pi-Cardia · BIOPROTECT · CardioValve · VenusMedtech · tixel · remilk. · ImaginDairy · WeGROW

CONTACT US

For tailored solutions that meet your company's needs, reach out to us:

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Partner with ProTechTiv to drive your projects forward with expertise and precision.
Thank you for your consideration.

Shlomi Avraham
CEO & Owner