

Michael Fainshtein

Chief Operating Officer | VP of Operations | COO | VP of Business Development

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Patents: <https://patents.justia.com/inventor/michael-fainshtein>

Medical Devices: https://youtu.be/Me_D3JtgrgM?feature=shared

Executive Summary

Senior operations and technology executive with 20+ years driving scale, compliance, and commercialization across biotech, MedTech, and fintech. Led global teams to deliver FDA-cleared products, build ISO-certified QMS, and grow revenue from \$1M to \$7M in under two years. Managed P&L, ERP rollout, and cross-border supply chains. Raised over \$30M in venture capital. Proven in building from zero to exit, under pressure, across borders.

Core Competencies

- Strategic Operations & Manufacturing Scale-Up
- Fundraising & Investor Relations (\$30M+ Raised)
- Regulatory Compliance (FDA, ISO 13485, CE)
- Cross-Border Partnerships & Post-M&A Integration
- Product Development & Innovation (20+ Medical Devices)
- Global Supply Chain, ERP & Quality Systems
- FinTech & MedTech Infrastructure
- Leadership in Crisis & High-Stakes Environments

Key Operations Wins

- Built ISO 13485-compliant manufacturing line supporting rapid production of cell therapy tools, including bioreactors and electroporators.
- Developed and deployed ERP-integrated quality systems across U.S. and EU manufacturing hubs.
- Reduced device production cost by 27% through vendor consolidation and DFM process optimization.
- Managed cross-functional engineering, regulatory, and logistics teams (45+ FTEs) across 4 time zones.

Selected Achievements

- Scaled biotech manufacturing from \$1M to \$7M revenue in 2 years through engineering optimization and SOP deployment.
- Led development of 20+ diagnostic and therapeutic medical devices, including CAR-T support systems and mobile BSL-3 labs.
- Built secure fintech infrastructure, increasing monthly transactions to 2M+ and user base by 800%.
- Secured \$15M+ funding for fintech/biotech startups through strategic investor engagement in the U.S., EU, and Asia.

Professional Experience

VP Operations / Head of Engineering – Mircod & Mircod Biotech Group

May 2015 – Jan 2025 | Global Operations

- Led operations for biotech/MedTech product development, regulatory strategy, and global manufacturing.
- Oversaw FDA submissions, ISO 13485 QMS buildout, and international supplier management.
- Directed manufacturing of bioreactors, electroporation tools, and diagnostic instruments.
- Developed ERP and quality control frameworks supporting scalable growth and compliance.
- Forged strategic partnerships with EU and Japanese corporates for product co-development.

Chief Engineer / Co-Founder – Luma Strike Inc.

Jan 2013 – Mar 2015 | Product Strategy & Market Growth

- Built data-driven development pipelines increasing engineering throughput and efficiency by 30%.
- Oversaw product roadmap and strategic planning with engineering and business teams.
- Managed operational transition from concept to launch for core product suite.

Founder & CTO – Finaro (CredoRax)

Apr 2008 – Jul 2011 | USA, IL, EU, CN, JP

- Architected payment infrastructure that scaled to handle 2M+ transactions/month.
- Expanded user base by 800% through secure fintech platform rollout across global markets.
- Raised \$15M in venture capital and led cross-functional engineering execution across 4 continents.
- Supported M&A prep and post-acquisition alignment efforts with strategic investors.

Education

- B.Sc. Electronics & Computer Science – ORT Engineering College, 2002

- RF Field Engineering Diploma – Jerusalem ORT, 1998

Technical Expertise

- Biotech / MedTech: CAR-T, Bioreactors, Mobile Labs, FDA / ISO Submissions
- FinTech: PCI-DSS, Blockchain, Fraud Prevention
- Tools: SolidWorks, Altium, MATLAB, LabView, AWS, Python, Git, TensorFlow

Certifications & Special Qualifications

- Cisco Security Engineer | IDF Navigation Systems
- TQM Certification | Advanced Diving & Rescue (Tec 60 CCR)
- Paramedic, CPR/AED Certified | Class D & G Armed Officer
- Certified Firearm Instructor (US and International)
- Certified Rescue Diver (IDF)