CONSULTANT PROFILE TEMPLATE
(LIFE SCIENCES ADVISORY)

Full Name:
Christopher R. Lotzow JD, RAC

Title / Role:
Principal Regulatory Advisor, Founder; Pathfinder Compliance Strategies LLC

Areas of Expertise:

- Regulatory Affairs (MDR and 510k marketing authorizations)
- Strategic regulatory planning from development through post-marketing
- Biocompatibility planning and documentation
- Biomaterials and xenograft expertise
- Marketing material strategy and review
- Entropy/deficiency/audit responses
- Change management – documentation and regulatory notifications

Professional Summary:
I work with clients to meet their needs across the range of services that will support their business goals and immediate needs. Whether a straightforward contracting arrangement is needed to address their internal resourcing challenges, or skills gaps exist that need to be closed in processes or submission content, my experience and insights are fully leveraged for the benefit of the client and the project.

My Regulatory Affairs experience in an innovative and development-driven biomaterials company is also available to clients as input that helps identify the strategic options that is compatible with their risk-tolerance. When welcomed by a bold or aggressive client, my work will expand the options available to them and will never restrict their options to a long and expensive conservative pathway simply because it was suggested by a regulator. As a personal rule, I do not, and will not ever, present AI-generated content as my own work.

Key Competencies:

- Strategic solutions matching stakeholder risk tolerance
- Biocompatibility programs including animal sourced tissues
- Creatively compliant marketing materials
- Identifying and presenting innovative compliance approaches

Industry Experience:

- Medical Devices and device-led combination devices
- Biotechnology and biomaterials
- CRO / Consultancy
- New product development
- Regulatory compliance across the entire product lifecycle

Selected Achievements / Project Experience:

- Created a new biocompatibility department to integrate with existing processes and ISO 13485 risk evaluation structure, facilitating auditor acceptance of the evaluation processes.
- Developed a comprehensive biological safety evaluation report structure for 5 MDR CE marks without a single substantive question on the report's content or determinations.
- Successful 510k clearances leveraging existing data with science-based justifications for relevancy, reducing the cost and time resources needed for the completion of the submission dossiers.

Education & Certifications:

- Bachelor of Science – Physics
- Attorney – JD, Mckinney School of Law
- RAC certifications – global devices and global pharmaceuticals
- Registered Patent Attorney, USPTO
- Journeyman Tool and Die Maker

Regulatory / Technical Expertise (if relevant):

- FDA
- EMA
- 510k clearances
- MDR / MDD CE marks
- BSI medical device MDR CE marks
- TUV medical device MDD CE marks
- Global regulatory technical filings

Languages:

- English – native speaker

Availability:

Available from May 1, 2026 for full time, part time, and project-based contracts

Location / Willingness to Travel:

Located in Midwest US, Eastern time zone. Will match customer's work hours and can travel as requested by client.

Contact / Booking:

Contact email: pathfinderstrategiesllc@gmail.com
Contact directly by phone at: +1-765-577-0174