

Risk-Based Approach

to FDA-regulated environments



Global regulatory

landscape

Global Quality Systems design | strategy | deployment

Since 1998

Full spectrum of FDA-regulated environments

Pharma

Med Device

Biotech

Nutraceuticals

The Spanos Group is a leading provider of Regulatory Affairs Compliance, Validation, Quality and auditing services to FDA- regulated organizations. Areas of knowledge include:



21 CFR Part 210/211 - Good Manufacturing Practices



21 CFR Sub Chapter H - Medical Device Regulations



21 CFR Part 820 - Quality Systems Regulations



ISO 13485 - Medical Devices



CAPA/Non-conformity



21 CFR Part 11 - Electronic Signatures & Electronic Records



21 CFR Part 58 - Good Laboratory Practice for Nonclinical laboratory studies



EMA - European Medicines Agency

Our team of deployable experts are well-versed in remediating 483's, Warning Letters, and Consent Decree challenges using the latest up-to-date guidance with maximum emphasis on cost efficiency for our clients.



Specific

expertise

## Did you know?



Our clients save an average of 28% on their project budget

92%

of our clients recommend us to internal stakeholders



Spanos SMEs have successfully delivered well-over 900 project close-outs

Reliable and proven expertise across the full spectrum

*Data Integrity*

*Mock audits/Audit Readiness*

*Gap Analysis/Root Cause Investigations*

*Engineering Design Qualification*

*Full GxP systems validation*

Whether your business is R&D, pilot-scale, or full-scale production, you can benefit from both the broad experience offered by our compliance practice: Training, Regulatory Compliance, Validation, and Product/Process Development. In addition, we rely on an extensive global network of professionals in system design, validation, and 21 CFR Part 11 with Compliance Managers to assist with equipment, packaging lines, PLC's, SCADA's, BAS, LIMS, MRP, and SAP systems.



Part 11  
Compliance



13485:2016



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

Proven service

and credibility



Over 6,500 subject-matter-experts  
and deployable consultants in our  
global talent network



Veteran-owned company with a  
certified commitment to service,  
integrity and ethical business practices

80%

We've successfully managed projects  
within 80% of the Top 50 biopharmas  
and med device companies in the world

For more information on how we can partner with you, contact  
[solutions@thespanosgroup.com](mailto:solutions@thespanosgroup.com) and connect with us on *LinkedIn*.

[www.thespanosgroup.com](http://www.thespanosgroup.com)

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