Touchstone Technologies Silicon Valley

Regulatory Compliance Consulting & Training

Touchstone Technologies, Inc. Course Catalog February 2017

Angela Bazigos

Touchstone Technologies Silicon Valley

Regulatory Compliance Consulting & Training

HR Courses

Course Name	Course Type	Duration	Audience	Speaker
1. Basics of Project Management	Webinar	90 mins	Management	Bazigos
2. Project Management for 21 CFR 11	Webinar	90 mins	Management	Bazigos
3. Advanced Project Management	Seminar	2 days	Management	Bazigos
4. Dealing with Difficult People	Seminar	2 days	ALL	Bazigos
5. Unraveling the Mystery: Why some companies struggle while others succeed	Webinar	60 mins	C-Suite, Senior Management	Moukadam
6. Cybersecurity	Webinar	60 mins	C-Suite, Senior Management	Williams

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General Regulatory Courses

Course Name	Course Type	Duration	Audience	Speaker
1. European Data Protection Reform	Webinar	90 mins	ALL	Bazigos
2. Writing Effective SOPs	Webinar	90 mins	ALL	Bazigos
3. Quality by Design	Webinar	90 mins	ALL	Bazigos
4. Business Continuity Planning & Disaster Recovery	Webinar	90 mins	ALL	Bazigos
5. Change Management	Webinar	90 mins	ALL	Bazigos
6. Deviation Management	Webinar	90 mins	ALL	Bazigos
7. How to Select & Manage Vendors in a Regulated Environment (incl. ICH E6)	Webinar	90 mins	ALL	Bazigos
8. Corrective & Preventive Action (CAPA)	Webinar	90 mins	ALL	Bazigos
9. E-Submissions & Data Standards for FDA - eCTD, CDISC, HL7	Webinar	2 hrs	ALL	Bazigos
10. Drug Discovery & Development: the FDA Way	Webinar	90 mins	ALL	Bazigos
1. Good Documentation Practices SOP		45 mins	ALL	Bazigos
2. Change Management SOP		90 mins	ALL	Bazigos

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Cloud Courses

Course Name	Course Type	Duration	Audience	Speaker
1. Regulatory Compliance in the Cloud	Webinar	90 mins	Cloud	Bazigos

FDA Inspections

Course Name	Course Type	Duration	Audience	Speaker
1. FDA Inspection Program Overview	Webinar	90 mins	ALL	Bazigos
2. Key Factors for a Successful FDA Inspection	Webinar	90 mins	ALL	Bazigos
3. Quality System Readiness	Webinar	90 mins	ALL	Bazigos
4. Information Readiness	Webinar	90 mins	ALL	Bazigos
5. Organization Readiness	Webinar	90 mins	ALL	Bazigos
6. Manage FDA Inspection Outcomes	Webinar	90 mins	ALL	Bazigos
7. Managing Regulatory Risk	Webinar	90 mins	ALL	Spears
8. FDA's 21 CFR 11 Inspections	Webinar	90 mins	ALL	Bazigos
9. Medical Device Inspections	Webinar	90 mins	ALL	Bazigos
10. Food Facility Inspections	Webinar	90 mins	ALL	Bazigos
11. How to respond to 483s and Warning Letters	Webinar	90 mins	ALL	Bazigos
12. FDA Quality Metrics	Webinar	60 mins	ALL	Bazigos
13. How to Host and Respond to an FDA Inspection	Seminar	2 days	ALL	Bazigos / Spears

HIPAA Compliance

HIPAA Compliant

Course Name	Course Type	Duration	Audience	Speaker
3. HIPAA Best Practices	Seminar, Webinar	6 hours	Healthcare Security	Bazigos

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Vaccines

Course Name	Course Type	Duration	Audience	Speaker
1. General Principles of Clinical Vaccine Development	Webinar	90 mins	Clinical Assay Validation	Bazigos

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Method Validation

Course Name	Course Type	Duration	Audience	Speaker
1. Analytical Method Validation Process	Seminar	6 hours	Clinical Assay Validation Personnel	Bazigos

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Data Integrity / 21 CFR 11[1]

Course Name	Course Type	Duration	Audience	Speaker
1. 21 CFR 11 Basic Concepts	Webinar	90 mins	IT / QA	Bazigos
2. Risk Assessment for Computer Systems	Webinar	90 mins	IT / QA	Bazigos
3. Auditing Software Vendors	Webinar	90 mins	IT / QA	Bazigos
4. Validation Plan for CSV	Webinar	90 mins	IT / QA	Bazigos
5. Writing Effective Requirements	Webinar	90 mins	IT / QA	Bazigos
6. Writing Effective Design Documentation	Webinar	90 mins	IT / QA	Bazigos
7. Traceability Matrix	Webinar	90 mins	IT / QA	Bazigos
8. Software Test Plan and Software Test Report	Webinar	90 mins	IT / QA	Bazigos
9. The "Qs": IQ, OQ, PQ	Webinar	90 mins	IT / QA	Bazigos
10. Validation Report for CSV	Webinar	90 mins	IT / QA	Bazigos
11. Validation Registry and Completeness of CSV	Webinar	90 mins	IT / QA	Bazigos
12. Jeopardy Quiz – Test your 21 CFR 11 / CSV Knowledge	Webinar	30 mins	IT / QA	Bazigos
13. Excel Spreadsheet 21 CFR 11 Compliance	Webinar	90 mins	IT / QA	Bazigos
14. Test Tools for CSV	Webinar	90 mins	IT / QA	Bazigos
15. Infrastructure Qualification for 21 CFR 11 Compliance	Webinar	90 mins	IT / QA	Bazigos
16. Systems Inventory & Master Planning	Webinar	90 mins	IT / QA	Bazigos
17. Software Development / CSV	Webinar	90 mins	IT / QA	Bazigos
18. Data Integrity – Beyond 21 CFR 11 & Annex 11	Seminar	2 days	IT / QA	Bazigos
19. Data Integrity for Excel	Seminar	2 days	IT / QA	Bazigos

[1] Also see FDA Inspections

Medical Devices [2]

Course Name	Course Type	Duration	Audience	Speaker
20. Overview of Regulatory Requirements for Medical Devices	Webinar	90 mins	Medical Devices	Bazigos
21. Regulatory Overview of Device Establishment and Registration	Webinar	90 mins	Medical Devices	Bazigos
22. PreMarket Notification (510(k)) Program	Webinar	90 mins	Medical Devices	Bazigos
23. DeNovo Program	Webinar	90 mins	Medical Devices	Bazigos
24. Investigational Device Exemption (IDE) Basics	Webinar	90 mins	Medical Devices	Bazigos
25. Strengthening the Medical Device Clinical Trial Enterprise	Webinar	90 mins	Medical Devices	Bazigos
26. FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations	Webinar	90 mins	Medical Devices	Bazigos
27. The Sponsor's Responsibilities in Medical Device Clinical Trials	Webinar	90 mins	Medical Devices	Bazigos
28. The Clinical Investigator's Responsibilities in Medical Device Trials	Webinar	90 mins	Medical Devices	Bazigos
29. Computerized Systems Used in Medical Device Clinical Investigations	Webinar	90 mins	Medical Devices	Bazigos
30. Medical Device Classification and Reclassification Procedures	Webinar	90 mins	Medical Devices	Bazigos
31. The Unique Device Identification Program (UDI 101)	Webinar	90 mins	Medical Devices	Bazigos
32. Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)	Webinar	90 mins	Medical Devices	Bazigos
33. Designing Protocols for Pivotal Clinical Investigations	Webinar	90 mins	Medical Devices	Bazigos
34. MDUFA III	Webinar	90 mins	Medical Devices	Bazigos
35. Export Certificates for Medical Devices	Webinar	90 mins	Medical Devices	Bazigos
36. Exploring the FDA Refuse-To-Accept (RTA)	Webinar	90 mins	Medical Devices	Bazigos
37. How the FDA are trained for Medical Device Inspections	Webinar	90 mins	Medical Devices	Spears

[2] Also see GLP/GCP/GMP in Pharma, FDA Inspections, General, Data Integrity

Food[3]

Course Name	Course Type	Duration	Audience	Speaker
1. Food Facility Inspections	Webinar	2 hours	ALL	Bazigos

[3] Also see FDA Inspections, Data Integrity

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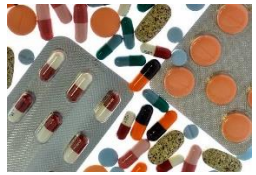
Pharma



Course Name	Course Type	Duration	Audience	Speaker
1. Risk Management & Drug Surveillance	Webinar	90 mins	ALL	Bazigos
2. Good Laboratory Practice – Basic Concepts	Webinar	90 mins	GLP[4]	Bazigos
3. Good Clinical Practice – Basic Concepts	Webinar	90 mins	GCP[5]	Bazigos
4. Regulatory Compliance in Pharmaceutical Supply Chain	Webinar	90 mins	GMP[6]	Bazigos
5. US, EU & Japan GMP Requirements - Practical ICH Area Differences & HealthCare Authority Inspection Focus	Webinar	90 mins	GMP	Bazigos
6. Lean Documents for Manufacturing in LifeSciences	Webinar	90 mins	GMP	Bazigos
7. Correction & Prevention of Human Error in Manufacturing	Webinar	90 mins	GMP	Bazigos

[4] GLP = Good Laboratory Practice
[5] GCP = Good Clinical Practice
[6] GMP = Good Manufacturing Practice

Cosmetics[7]

Course Name	Course Type	Duration	Audience	Speaker
1. Cosmetics – How Are They Regulated		90 mins	Cosmetics	Spears

[7] Also see FDA Inspections

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Pharmacogenomics

Course Name	Course Type	Duration	Audience	Speaker
1. Regulatory Issues in Pharmacogenomics	Webinar	90 mins	Pharmacogenomics	Bazigos

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OUR SPEAKERS

ANGELA BAZIGOS

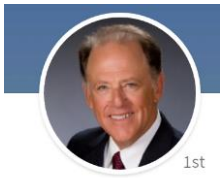
Angela has close to 40 years of experience in the Life Sciences & Healthcare Industries. Experience combines Quality Assurance, Regulatory Compliance, Business Administration, Information Technology, Project Management and Science and Turnarounds. Co-authored & prototyped 21 CFR 11 guidance with FDA. Co-authored Computerized Systems in Clinical Research w/ FDA http://www1.diahome.org/~/media/4FA562336EBD46C58CDC43A8B7773095.ashx Patent on speeding up software compliance https://www.google.com/patents/US8266578 . Recently quoted in Wall Street Journal for using training to bring regulatory compliance to the Boardroom http://blogs.wsj.com/riskandcompliance/2015/07/24/using-training-to-bring-compliance-to-boardrooms/ National Trainer for Society of Quality Assurance. Comments / collaborates with FDA on new guidance documents. Former President of Pacific Regional Chapter of Society of Quality Assurance. Stanford's Who's Who for LifeSciences: http://www.stanfordwhoswho.com/Angela.Bazigos.7144112.html#overview .

BAHAA MOUKADAM

Bahaa Moukadam is a former Silicon Valley CEO with an extensive track record of success. He led three for three successful turnarounds in high tech including one as the CEO of a Silicon Valley company. As a leader in three hyper-growth situations, he achieved explosive revenue growth from $0-$40M in 5 years; $60M to $173M in 3 years, and $0-$10M in one year. Bahaa is a Certified Gazelles International Coach and a contributor to Verne Harnish's best selling book *Scaling Up.*

Larry Spears

Larry Spears has deep regulatory expertise from over 35 years' experience in government and consulting. This includes investigations, compliance and regulatory roles with FDA including senior compliance leadership positions in the CDRH Office of Compliance, as a consultant with a large life sciences consulting firm and as an independent consultant. Mr. Spears provides global regulatory strategy consultation to Life Science companies primarily in medical devices/diagnostics and pharmaceuticals with a focus on quality systems gap assessments, FDA mock inspections, quality system development and planning, and remediation for FDA inspection findings including, CAPA and complaints, design controls, supplier controls, production management, and training



Rick Williams

Rick Williams helps leaders make important decisions. His unique insights are most valuable at critical junctures – creating a viable business model, preparing to raise capital, working to overcome barriers to growth, preparing for an acquisition, preparing to be acquired, or strengthening team function and leadership.
Rick's breadth of experience, including medical technology, financial services, real estate, management consulting and public/private engagement developed through his wide-ranging roles as an executive and board director enables him to understand quickly the essential drivers of a company or business opportunity. Purpose, issues, context, options, risks and clarity are what Rick brings to the table for the decision makers.
Rick's thought leadership is shared through national publications and speaking events.

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