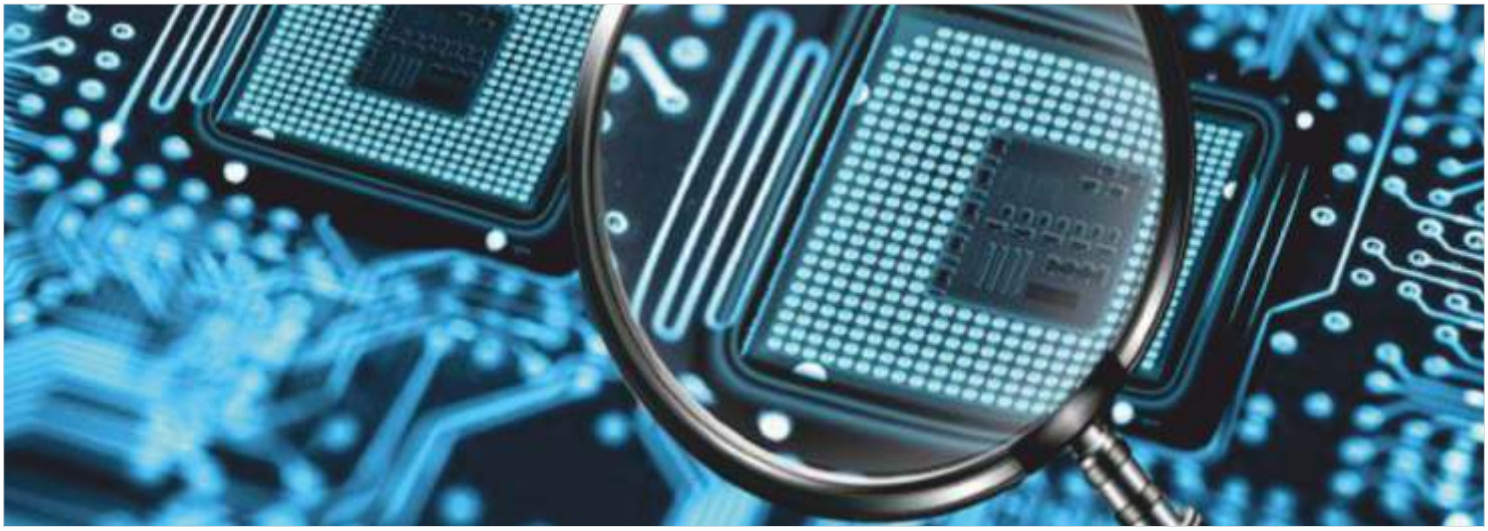
2-day In-person Seminar:

Verification and Validation - Product, Equipment/Process, Software and QMS: Compliance and Governance

By: David R. Dills

Location: Sydney, Australia | November 10th & 11th, 2014

Course "**Verification and Validation - Product, Equipment/Process, Software and QMS: Compliance and Governance**" has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification upon full completion.



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Global CompliancePanel

2-day In-person Seminar 2014

Overview:

This seminar will provide an overview and in-depth snapshot of the process for managing V&V activities affecting product, process, equipment and the QMS. Company employees responsible for new product development, regulatory submissions, initiating/overseeing company-wide V&V planning, using a risk-justified approach and responsible for some of the areas identified herein, certainly will benefit. Employees who will benefit include all levels of management and departmental representatives from key functional areas and those who desire a better understanding or a "refresh" overview of the V&V process with product, process, software and impact on the QMS from start to finish, with key emphasis on regulatory compliance and governance, including.

David R. Dills
Regulatory Affairs & Compliance Consultant

David R. Dills, Regulatory & Compliance Consultant with more than 24 years of hands-on experience and a proven track record within the FDA regulated industry, has an extensive regulatory and compliance background with Class I/II/III and IVD devices, pharmaceutical operations, and manages activities within the global regulatory and compliance space. . He manages quality, regulatory and compliance projects with multiple competing priorities having a direct impact on site operations and commercial opportunities and develops strategies for governmental approval to introduce new products to market, provides guidance on regulatory and compliance requirements and prepares/reviews worldwide submissions/dossiers/technical files and addresses global regulatory requirements.

Agenda:

Day 1:	Day 2:
Lecture 1: Regulatory and Compliance Overview/FDA Snapshot on V&V for Manufacturers/Master Validation Planning	Lecture 7: Software V&V documentation
Lecture 2: FDA's approach and Risk Management Tools with ISO 14971, ICH and other Guidance/Standards - Product, Process Equipment V&V	Lecture 8: Software V&V protocols and summary reports
Lecture 3: Product/Device V&V	Lecture 9: Electronic Records and Electronic Signatures (Part 11)
Lecture 4: Software V&V and where and how does software validation integrate into the Validation Plan	Lecture 10: Course summary discussion
Lecture 5: Quality Management System/21 CFR Part 11 expectations and requirements	Lecture 11: Review of group activity and hands-on examples and activities show real-world implementation of useful governing principles, tools and templates and the most recent enforcement actions for trending, compliance and governance
Lecture 6: Avoid or Minimize Compliance Concerns and Issues: Q&A/FAQs and review of company documentation	

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GlobalCompliancePanel Seminar Registration Form

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Price for One Delegate pass Price: $1,595.00

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Email: support@globalcompliancepanel.com

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Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar

Team GlobalCompliancePanel

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GlobalCompliancePanel Seminar Registration Form

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If GlobalCompliancePanel cancels an event, we will not be reimbursing any airfare, accommodation, other costs or losses that the registrants may have incurred. GlobalCompliancePanel reserves the right to change topics and speakers without notice.

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