



Thursday 30th July 2015

Data Integrity

The PDA Australia Chapter is pleased to invite members and non-members to attend our dinner meeting on Data Integrity. Learn more about this Hot Topic from leading experts, including the TGA, who will help you identify best practices in DI. Hear about what Regulators are expecting, auditing tips and preventative measures for DI.

Speakers:

Stephen Hart – TGA

Data Integrity: TGA Expectations

Stephen Hart is a Senior Inspector of the Manufacturing Quality Branch (MQB), within the Monitoring and Compliance Division of the Therapeutic Goods Administration (TGA), Department of Health. Stephen has worked for the Therapeutic Goods Administration (TGA) for over 10 years as a Senior Inspector, performing GMP compliance inspections both within Australia and overseas.

Mark Dickson – Novartis

Data Integrity Audits: common pitfalls, expectations and experiences

Mark Dickson is a Senior Compliance Professional with Novartis since Feb 2013. He has a global corporate role reporting to Novartis Pharma AG within the Pharma Auditing and Compliance Group. Mark previously worked for the TGA and has more than 25 years experience in the pharmaceutical industry in Australia and overseas.

Trevor Schoerie – PharmOut

Data Integrity: Success by Design, Fat-finger, Falsification and Fraud

Trevor Schoerie is PharmOut's Managing Director and founder. Trevor has held executive and functional operational management roles in a diverse range of industries in the pharmaceutical, food, automotive and chemical industries in various quality, manufacturing, validation, engineering and more recently consulting roles. Trevor understands the business pressures that can arise from regulatory requirements, his vision is to provide industry with practical, cost-effective solutions to regulatory challenges.

Venue:

L'unica on Parkville

476 Brunswick Road, Parkville, Vic 3052, T: 9388 9955

Note: Parking is available on site

Agenda:

5:30pm

Arrival

6:00pm

Presentations

7:30pm

Dinner

Fees:	PDA Members \$80	Non Members \$110
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Registration

Registration and payment must be received by July 23rd 2015 to secure attendance. Please register early as places are limited!

If you have any special dietary requirements, please advise us prior to the event.

1. On-line Registration and Payment by Credit Card:

Click on link to Register: <http://www.trybooking.com/IDTO>

Payment can be made by Visa or Mastercard and a receipt will be issued (inc. 30c processing fee).

2. Manual Registration and Payment by EFT:

Complete the form below and email to David Spaulding (david.spaulding@seerpharma.com.au)

Meeting booking form and Invoice ABN 89 007 789 459

PDA Australian Chapter

Direct Payment to: NAB Box Hill No: 083 153, Account No: 13555 3091

**This form is an invoice. Once payment is received this registration form becomes a receipt.
Note: PDA is not required to charge GST therefore a tax invoice is not required.**

Name and email address	Member (Yes/No)	Membership Number	Amount (\$)
Company:			
Phone:			

SPECIAL NOTE:

Our records show that there have been a number of companies, PDA members and non-members who have not paid for previously attended events. Those wishing to register for future events will be asked to pre-pay to secure attendance.