

# Available now!

## The TOPRA Guide to Careers in Regulatory Affairs



### The TOPRA Guide to Careers in Regulatory Affairs

**Edited by:** Jenine Willis

With contributions from Susan Botfield, Tony Cartwright, Graham Donaldson, Ming Ewe, Debbie Finlay, Paul Foster, Michael Holzhauser-Alberti, Craig McCarthy, Angela Miller, Sarah Roberts, Heimo Scheer, Davina Stevenson, Nick Sykes, Hilde Viroux, Lynda Wight

**Published by:** TOPRA Publishing, London, UK

**Book:** Paperback, 56 pages

**Price:** £15, €18, US\$25

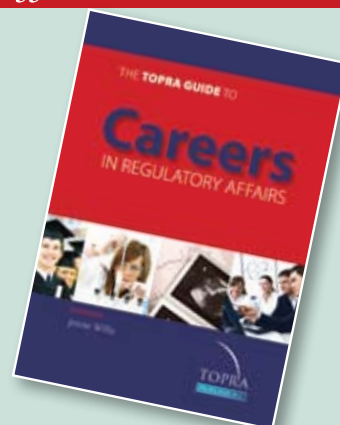
**ISBN:** 978-0-9564943-1-3

- Do you want to work in a business sector that can influence the health and well-being of millions of people?
- Do you want to be able to constantly extend your scientific and legal knowledge?
- Do you want to work with intelligent, driven colleagues on projects that challenge your thinking and allow you to stretch yourself?
- Do you want to exercise personal skills in a role that has exciting career opportunities to the highest level?

If you think a career in healthcare Regulatory Affairs could be for you, then this is the guide to read before you go any further! Due to popular demand TOPRA – the European Regulatory Affairs professional organisation – has pooled together a wide variety of experiences and advice from professionals who already work in Regulatory Affairs. Our contributors range from Vice Presidents in industry with years of regulatory experience to professionals who have just started on the regulatory career ladder. We have perspectives from pharmaceuticals, medical technologies, veterinary, consultants and regulators.

Regulatory Affairs is an international endeavour and there are great opportunities to travel and work abroad. However, the country where you are based, type of company you work for or your specialty will shape your day-to-day working environment. Although our content is focused on the European regulatory sector, the experiences of Regulatory Affairs share common threads as you will read.

This booklet is aimed at graduates and postgraduates looking to enter the healthcare regulatory world – be it in pharmaceuticals,



medical technologies or veterinary sectors. Whichever specialty you choose, this dynamic environment provides an interesting, challenging and rewarding career for those who have the drive, the right qualities and qualifications. *The TOPRA Guide to Careers in Regulatory Affairs* will help to get you on the right track and TOPRA itself can help to support you as you make your first steps in your new career. For further information go to [www.topra.org](http://www.topra.org).

### Evaluating Medicines – Perspectives from A European Regulatory Authority

**Edited by:** DS Slijkerman, JM van Ree, RTW Meijer and EMA Breeveld

**Published by:** TOPRA Publishing, London, UK

**Book:** Paperback, 116 pages

**Price:** £25, €30, US\$40

**ISBN:** 978-0-9564943-0-6

**Topics include:**

- How medicinal products get onto the market
- European market for medicinal products
- Centralised registration and the role of the national authorities

TOPRA Publishing's first book is a collaboration with the Medicines Evaluation Board of The Netherlands (Dutch MEB). *Evaluating Medicines* was originally published in 2008 in Dutch under the title *Openheid van zaken – De werkzaamheden van het College ter Beoordeling van Geneesmiddelen*.

The authors come from a wide variety of backgrounds and expertise and offer valuable insight into the world of medicines. In this concise publication they explain in simple terms, the intricate nature of European Regulatory Affairs in order for this complex process to be understood and appreciated.

The book has been updated, translated into English and published by TOPRA Publishing so that it can reach a wider readership. It is aimed at anyone who wants to understand what the work of a leading European regulatory authority is really about.

Although written with the lay person

in mind, this book has something to teach those who are starting a career in Regulatory Affairs, those who work outside of the European system and need to understand it more fully, and even experienced EU regulatory professionals who would like to have a view from inside one of our leading agencies.

The translated version has not altered the original esprit, but provides an updated text which retains the clarity of the original. The authors express their own views candidly, which are not necessarily those of the MEB or TOPRA, in a way that will greatly add to an appreciation of the work of a busy EU agency. Although written from the perspective of those who work in just one of the EU member states, the issues and challenges they discuss are relevant across the region.



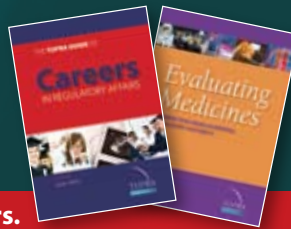
**ORDER YOUR COPIES TODAY USING THE ORDER FORM OVERLEAF**

email: [publications@topra.org](mailto:publications@topra.org) tel: +44 (0) 20 7510 2560 fax: +44 (0) 20 7537 2003 web: [www.topra.org/publications](http://www.topra.org/publications)

# ORDER FORM 2010

## Order your copy of The TOPRA Guide to Careers in Regulatory Affairs and/or Evaluating Medicines now!

Published by: TOPRA Publishing, London, UK



You can order via email, fax or phone. Discounts are available for bulk orders.

Please complete this order form in block capitals and return it with payment to TOPRA using one of the following methods:

**Post:** TOPRA Publishing, Bellerive House, 3 Muirfield Crescent, London E14 9SZ, UK **Fax:** +44 (0)20 7537 2003 **Email:** [publications@topra.org](mailto:publications@topra.org)

If you have any queries contact us on +44 (0) 20 7510 2560 or email [publications@topra.org](mailto:publications@topra.org)

I would like to purchase: **The TOPRA Guide to Careers in Regulatory Affairs**

**Edited by:** Jenine Willis

**Book:** Paperback, 56 pages

**Price:** £15, €18, US\$25

**ISBN:** 978-0-9564943-1-3

<b>No. copies</b>	<input type="text"/>	
Amount in <b>Sterling</b>	£ <input type="text"/>	or
Amount in <b>Euros</b>	€ <input type="text"/>	or
Amount in <b>US Dollars</b>	\$ <input type="text"/>	or

Significant discounts are available for multiple copies, email [publications@topra.org](mailto:publications@topra.org) or call +44 (0)20 7510 2560 for further details.

I would like to purchase: **Evaluating Medicines – Perspectives from a European Regulatory Authority**

**Edited by:** DS Slijkerman, JM van Ree, RTW Meijer and EMA Breeveld

**Book:** Paperback, 116 pages

**Price:** £25, €30, US\$40

**ISBN:** 978-0-9564943-0-6

<b>No. copies</b>	<input type="text"/>	
Amount in <b>Sterling</b>	£ <input type="text"/>	or
Amount in <b>Euros</b>	€ <input type="text"/>	or
Amount in <b>US Dollars</b>	\$ <input type="text"/>	or

For orders of six or more copies you can obtain a bulk buy discount, email [publications@topra.org](mailto:publications@topra.org) or call +44 (0)20 7510 2560 for further details.

**UK:** £2 for first copy, add £1 for each additional copy, up to five\*

**Eur:** €3 for first copy, add €1 for each additional copy, up to five\*

**US:** \$8 for first copy, add \$3 for each additional copy, up to five\*

\*Applies to one delivery address only.

<b>Postage costs</b>		
Amount in <b>Sterling</b>	£ <input type="text"/>	or
Amount in <b>Euros</b>	€ <input type="text"/>	or
Amount in <b>US Dollars</b>	\$ <input type="text"/>	or

Promotional code   
(If applicable)

Discount (If applicable)

**Total**

Dr  Mr  Mrs  Ms  Other

Family name

First name  Male  Female

Telephone

Fax

E-mail

**Delivery address**

(If different from billing address)

City  Postcode

Country

### Payment method

Cheque enclosed  Cheque No

Bank transfer

Invoice

Only applicable on bulk orders of 6 or more copies, which will all be delivered to one address supplied.

UK VAT reg. no.   
(If applicable)

Please charge my debit/credit card   
(Charged in Sterling only)

### Debit/Credit card details

(For cards accepted, see payment section below)

Debit Card  Visa  MasterCard  American Express

Card No

Expiry date  /

Security code  *Debit cards, Visa, MasterCard: the last 3 digits AFTER the card number in the signature area of the card.*

Name of card holder   
(as given on card)

Billing address<sup>†</sup>   
for card

City  Postcode

Country

<sup>†</sup>Billing address for card (must be provided if different from the delivery address)

TOPRA will seek authorisation from the card-issuing company before confirming any purchase (VAT Registration Number: GB 342 7398 40).

By signing below, I confirm that I agree with TOPRA's Terms & Conditions

SIGNATURE

DATE

### Terms and conditions *Please note: TOPRA's full Terms & Conditions are available on the website at [www.topra.org](http://www.topra.org)*

#### Payment:

- Cheques:** must be made payable to TOPRA and drawn on a UK bank in either Euro or Sterling or US Dollars.
- Debit/Credit card:** for payment by card please complete the relevant details above. Cards accepted: AMEX, Debit MasterCard, Delta, Electron, Maestro, MasterCard, Solo, Visa. All cards will be charged in Sterling from orders posted to the office.
- Bank Transfers:** may be made to Lloyds TSB Bank PLC. Please quote your name and the promotional code in the transmission details. Bank charges to be paid by the sender.
- Sterling Transfers:** Account No: 00340310, Sort Code: 30-00-09, IBAN: GB45 LOYD 3000 0900 3403 10, BIC LOYDGB21013

- Euro Transfers:** Account No: 86330987, Sort Code: 30-00-09, IBAN: GB19 LOYD 3000 0986 3309 87, BIC LOYDGB21013
- US Dollar Transfers:** Account No: 11652656, Sort Code: 30-00-09, IBAN - GB12 LOYD 3000 0911 6526 56, BIC LOYDGB21013

#### Data Protection:

- We may occasionally send you promotional or other information about TOPRA's products and services. If you do not wish to receive this information, you can opt out of future communications by ticking this box
- We may occasionally send you promotional or product information from organisations and companies other than TOPRA. If you do not wish to receive this information, you can opt out of future communications by ticking this box

TOPRA – The Organisation for Professionals in Regulatory Affairs Ltd. Registered in England number 1400379. A Company Limited by Guarantee. TOPRA is the registered trademark of The Organisation for Professionals in Regulatory Affairs Ltd, Registered Community Trademark number 003182961. The TOPRA logo is covered by The Community Design registration numbers EU Des Reg number 00005553-0001 and 0002.

email: [publications@topra.org](mailto:publications@topra.org) tel: +44 (0) 20 7510 2560 fax: +44 (0) 20 7537 2003 web: [www.topra.org/publications](http://www.topra.org/publications)