EIPG GUIDANCE ON CPD for RA

Continuous professional development for regulatory affairs

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A. Introduction

Continuing Professional Development (CPD) is a combination of approaches and techniques used to continuously develop and maintain knowledge and personal qualities needed to perform a role. It is life-long, and allows the individual to take responsibility for their own personal and career development.

Maintaining competence throughout a career, in which new and challenging professional responsibilities will be encountered, is a fundamental ethical obligation for all those working in the pharmaceutical industry. In any marketing authorisation application in the EU the applicant has to confirm that '*all existing data which are relevant to the quality, safety and efficacy of the medicinal product have been supplied in the dossier, as appropriat*e'. Furthermore, there is a general requirement (Article 23 of Directive 2001/83/EC) on Marketing Authorisation Holders to *'…take account of scientific and technical progress and introduce any changes that may be required to enable the medicinal product to be manufactured and checked by means of generally accepted scientific methods…'.*

Additionally, pivotal to Regulatory Affairs and Good Regulatory Practice (GRP) is the need to keep abreast of world-wide legislation, technical and regulatory guidance including potential changes and the interpretation of them in relation to possible consequences for the company regarding new product development, life-cycle management of the portfolio or possible impact in the event of failure to meet requirements.

All of this can be achieved by undertaking Continuing Professional Development (CPD) which is a tool used to demonstrate an individual's ability to perform in a role as well as being used to further career development.

Regulatory Affairs is a very different career now compared to its inception as a professional role in the 1960s. There is now a broad range of technical, strategic and managerial regulatory roles as well as many new opportunities for regulatory professionals to become involved with different types of companies in the pharmaceutical industry (e.g., in terms of product portfolio such as drug substance manufacturers, research-based companies, generic companies etc.), their contractors and consultants. Now more than ever, regulatory affairs professionals are responsible for their own career development and can take their career in whichever direction they choose.

B. What are the benefits of CPD for the individual?

It will provide professionals of RA professionals with a more systematic way to analyse and review the development needs of their staff.

Employers and clients of contract/consulting companies will obviously particularly value RA professionals who have a commitment to CPD.

RA professionals that adhere to the principle of CPD will be more valued by their employers. The collaboration of the company the RA professionals is working for is very important, in order to get training courses.
A positive evaluation after CPD activities also helps to motivate the Regulatory Affairs personnel

The growing CPD record will form an invaluable part of the Curriculum Vitae (CV) of the RA professional and it is therefore in their interest to keep this record up to date.

C. What is CPD?

CPD includes attending formal in-house or external training courses or workshops but is also a much broader concept which includes amongst a number of "soft skills" also the following:

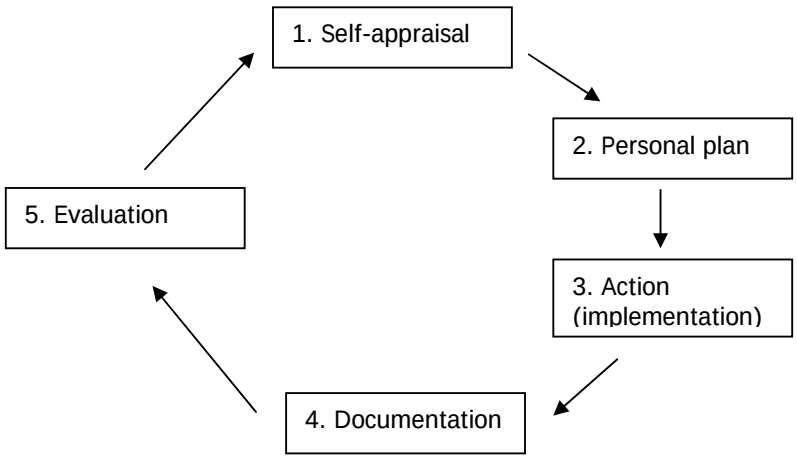
Being mentored by a more senior colleague in some new aspect of regulatory work;
Consulting the Internet for new or existing information and guidelines from the regulatory agencies on procedures, technical requirements for filings etc;
Consulting the Internet for regulatory intelligence (e.g. precedents from other companies' submissions and approvals);
Reading technical and professional publications (e.g. TOPRA Regulatory Rapporteur);
Reading books and articles about "soft skills" (e.g. influencing, decision-making, negotiations) and management;
Preparation of presentations;
Preparation of publications;
E learning;
Work-based projects and short term role/department attachments;
Non work-related activities such as voluntary work or coaching a team etc. especially when working on interpersonal or leadership skill areas;
Attending industry or agency working party meetings;
Being coached.

D. The five step cyclical process for CPD

CPD must be an ongoing cyclical process of continuous improvement, in which the Regulatory Affairs professional seeks to improve and maintain their technical knowledge and personal qualities for the current and any future roles. CPD is not just Continuing Education (CE) although this can have an important role in fulfilling CPD needs.

A structured CPD programme must be actively managed to be effective and may include the following five steps:

1. Self appraisal
2. Personal plan
3. Action (implementation)
4. Documentation
5. Evaluation



1. Self appraisal

The identification of CPD needs may arise from one or more of the following:

- Personal assessment of performance
- Performance review by professional/peer
- Professional/company requirement for keeping current
- Career development for future portfolio opportunities of the company or for a future role

2. Personal plan

This identifies the resources and actions required to meet the personal CPD needs identified in step 1. A whole list of options can be identified. Examples of possible resources or actions are:

- Identification of possible training course(s)
- Research into information/literature/references to support
- Identification of colleague/peers who could provide advice
- Previous work experiences

3. Action

In this step the intentions of step 2 are brought into practice: from step 2 the chosen resource or action is undertaken. This could be in the form of:

- Mentoring/work-shadowing
- Training course(s)
- Professional qualifications
- Informal discussions with colleagues
- Participation in professional body working groups
- Reading and other research

4. Documentation

For the reasons identified previously, it is important to document all CPD activities undertaken so that this can be provided as evidence of competence. Company records often merely consist of 'training records' so it is important that other types of CPD are systematically recorded.

Some regulatory bodies or national professional bodies may require all aspects of appraisal, planning, action and evaluation to be systematically recorded and then made available for review and inspection. Others may simply require the CPD actions themselves to be recorded.

5. Evaluation

Benefit from participation in any CPD activity should be evaluated. The professional RA should review in how much the action step has covered (or exceeded) the professional plan step. Possible questions to ask include:

- Were my needs addressed?
- Can I address what I learned?
- How will my work improve?
- What else can I do to support my learning?

This step also needs to be documented properly.

E. Regulatory affairs knowledge

General note:
It cannot be expected that each RA professional knows all that is defined in the document but the relevant pieces to his/her job need to be defined and adhered to with this document as guidance.

1. Gaining marketing authorisations for new drugs/ establishing the best regulatory strategy, new indications, etc.

It is the responsibility of the regulatory affairs professional to establish a regulatory strategy assessment for all new drug product developments, preferably starting once pre-Phase 1 is initiated. This assessment will be a continuously evolving document that will be adapted and revised on a regular basis to include and address any new information and data gained. It takes into account the necessities and requirements of the non-clinical testing, the different clinical Phases including Phase I – III and the regulatory requirements to compile a complete marketing authorisation application dossier, which fulfils the current requirements. Consequently, the regulatory affairs professional has to ensure that any new guidelines and legislations are reflected in the assessment document and that appropriate actions are initiated at an appropriate timing.
The assessment may also address particular needs of the different regions Europe, US and Japan (if applicable) and additional requirements of the rest-of-world countries.

These assessments will continue as part of the life-cycle management of existing drug products, i.e. it will include appropriate assessment of Phase IIIb and Phase IV studies for existing indications but also additional clinical and non-clinical development for new indications as well as pharmaceutical development activities to include new dosage forms or new strengths.

The main emphasis needs to be put on optimising the regulatory strategy e.g. the choice of the approval procedure used, in order to improve the chances of success resulting in the best SmPC in the shortest amount of time. The advantages and potential disadvantages of an application via a centralized procedure vs. a decentralized / mutual recognition procedure in Europe have to be carefully evaluated including the choice of (co)-rapporteur and reference member states.
The previous experiences gained from submissions of applications via different procedures is very important and the selection of the countries taking into account the needs of the company related to commercial issues has to be considered seriously also.
The previous deficiency letters and answers provided in a dossier is a good way to learn the requirements form different countries and Agencies.

The regulatory affairs professional will also ensure appropriate and adequate interaction with important regulatory authorities prior to submission of a new marketing authorisation application for new drug products or submission of a line extension. This may be done as part of scientific advice meetings or portfolio meetings.
Communication and negotiations with Regulatory Agencies are important to keep in the documentation system for any Development Program.

2. Maintaining existing authorisations

Responsibility for maintaining and updating existing authorisations includes preparation and submission of renewals of marketing authorisations, PSURs-handling, preparation and submission of Variations (pharmaceutical variations, modification of the product information, extension of indication) and post marketing authorisation commitments.

a) Renewals of marketing authorisation and PSURs-handling

- Renewals of marketing authorisations and PSURs submission should be carefully planned for the whole portfolio of the pharmaceutical company, with yearly check if any amendment to the planning is needed. Renewals and PSURs are closely linked (but independent processes) and

renewal submission dates can, in some cases, be amended in order to comply with the PSURs submission date.

b) Variations

As part of life cycle management changes to the Marketing Authorisation will be required. The extent to which variations will be needed especially in terms of the quality information provided (CMC section) relates directly to the level of detail originally submitted as part of the Marketing Authorisation submission. It is the responsibility of the regulatory affairs professional to assess the need for variations and advise on the supporting documentation needed as well as the best strategy for submitting them.

Knowledge of the CMC processes is also necessary to be able to understand what the dossier is about (basic level of manufacturing process knowledge, QC analysis methods, ...)

Depending on the rational leading to the possible changes such as control changes from the factory to adapt to its needs and / or commercial interests, or Pharmacopeia or guidelines update, the RA professional will:

- Assess the proposed manufacture and control changes for dossier impact.
- Ensure contact between the Company and Contract Service Providers regarding development of information impacting product registration in close cooperation with further departments such as production, quality control, quality assurance, etc.
- Identify the CMC information appropriate for regulatory dossiers including determination of suitable analytical specifications, method validation evaluation parameters and minimum stability data requirements.

Unless specified in the guidelines, supporting documentation needed for variations could change from one country to other in many cases, so in this point it is very important to get the advice from the different Agencies or customers of the concerned countries. The previous experience also becomes a good CPD activity in this point.

The 'soft skills' are also important in this point in order to identify the need for variations and the type of them (as well as consulting the guidelines) and to finally sort out the best filing strategy.

c) Post marketing authorisation commitments

Activities related to post marketing studies must be carried out in compliance with, and reported according to, existing legislation.

Regulatory affairs departments must have an updated knowledge of:

- Post-Authorisation Guidance
- Regulations regarding :
- Management of Post-approval Commitments of a Marketing Authorisation
- Specific Obligations and Follow-up Measures for the Management of the Marketing Authorisation

Regulatory affairs professional must also have a thorough understanding of the studies requested and must follow-up regularly their progress with the other departments involved to make sure that the commitments of the company will be fulfilled.

Remark: Line extensions are sometimes considered as part of the life-cycle management; as they need a separate marketing authorisation, a new registration file need to be submitted.

3. Regulatory intelligence

Regulatory legislation is continuously changing in order to reflect the current knowledge and scientific advances. Consequently, it is essential for the regulatory affairs professional to keep current in terms of regulatory documents such as guidelines and legislation. In addition, it is vitally important to also track any discussion on anticipated changes, which are presented as concept papers via the websites of the European Medicines Agency (EMEA), the International Conference on Harmonisation (ICH) or the US Food and Drug Administration (FDA). It is vital to regularly check the official announcements of the different regulatory institutions, such as the websites of the EMEA, the EC-Commission, the Head of Agencies for Europe and, when relevant, the respective websites of the national Health Authorities and Agency in the US etc. on a very frequent basis.

Since upcoming changes in the regulatory environment can be of major impact on the regulatory activities for the approval process and the life-cycle management of medicinal products, continuous evaluation of newly published guidelines etc. is of great importance and is one of the major tasks of a regulatory affairs professional.

In addition, pharmaceutical companies should be encouraged to contribute to the work of pharmaceutical associations on a national and a European level in order to position their view of any planned regulatory changes. This is of importance to increase the visibility of pharmaceutical industry in the issue and revision of regulatory documents.

A good documentation system should be maintained regarding update legislation and guidelines from all sources from EU, US, etc., in addition, preferably a part of the regulatory affairs department works in the research of this subject including its regular updates.

It is not only the regulatory affairs professional who has to be up-to-date in terms of any anticipated and proposed changes in the regulatory environment but it is also his duty to keep his colleagues in adjacent departments informed of any relevant changes in the regulatory environment. It is his responsibility to evaluate the potential impact of regulatory guidelines and legislation on the company's portfolio and initiate appropriate activities within the company. Within the scope of this "regulatory intelligence" he will be responsible to update his colleagues on a regular basis by issuing a regulatory newsletter and / or offering regular training sessions.

This responsibility is not only limited with regard to the colleagues of the site but especially applies to colleagues from other subsidiaries and the headquarters when located in different countries in terms of globally acting pharmaceutical companies. Especially for those companies a functioning and powerful system for continuous exchange of information on changes is of vital importance.

4. Archiving and tracking systems

Regulatory affairs departments have the responsibility to keep appropriate archiving and tracking systems to ensure traceability and appropriate timing of all regulatory activities.

a) Responsibility for keeping appropriate archiving

Regulatory affairs departments have to manage many documents (registration dossier, renewals, variations and amendments of the relevant part of the marketing authorisation dossier, change of SmPC/PIL, PSURs, requests from the health authorities and the answers submitted, regulatory texts).

Regulatory affairs departments must ensure full traceability of all the documents and the date of submission, approvals etc. and a clear archiving system. This may best be achieved by help of a commercially available electronic document management system, however each regulatory affairs

department can have their own tracking and archiving system adapted to the structure of the company and to the portfolio.

Regulatory affairs departments have the responsibility to:

- Review regularly and keep up to date, all regulatory documentation.
- Control that Amendments are dated, authorised and signed by the authorised persons.
- Organise an archiving system in order that all regulatory documentation is securely stored, protected against loss or damage and that only authorised personnel is allowed to enter or change data. Furthermore, documentation should be readily and easily accessible to regulatory affairs personnel.
- Organise and install an appropriate document retention policy regarding regulatory documents and submissions and the mandatory time period the documentation needs to be kept and stored.

b) Responsibility for keeping tracking systems to ensure appropriate timing of all regulatory activities

Regulatory affairs departments have to anticipate and schedule many activities with mandatory timing such as renewals and PSURs Submission, answers to health authorities during a registration, variation or renewal procedure, submission of study results when they are part of the post-marketing follow-up measures etc.

As above, Regulatory affairs departments have the responsibility to organise a tracking system of all the activities and related documentation with alarms to remind in advance the deadline taking into account the time needed for the constitution of the relevant activity. This can be achieved by help of a commercially available electronic document management system; however each regulatory affairs department can have their own tracking system adapted to the structure of the company and to the portfolio. The e-CTD tool, as an electronic document management/submission system, ensures harmonisation between all companies and countries.

The **'soft skills'** are also important in this point in order to make all departments comply with the dates and deadlines.

5. Additional Knowledge elements of Regulatory affairs departments

Regulatory affairs departments have the responsibility for ensuring the compliance of the relevant company's activities to the local and global regulations. Depending on the structure of the company (head-quarter or affiliate), its size, the local regulations, regulatory affairs departments can be responsible for and have current knowledge and thorough understanding in the activities described hereafter. A short description of the field of activities that might be concerned is given hereafter. However, these activities are not always under the responsibility of the RA professional, depending on the company structure and organization.

a) Promotional material Regulatory Control

In order to ensure the regulatory control of the advertising material, Regulatory affairs departments should have current knowledge of local regulations and health codes on advertising materials, on clinical trial methodology and interpretation of their results and should benchmark remarks or sanctions published by the health authorities or self-regulation industry bodies on other products to gain intelligence.

b) Pricing and reimbursement dossier

In some organisations, Regulatory affairs department can be deeply involved in obtaining the most optimised price and reimbursement arrangements. Knowledge in content of the dossier, of the key

parameters to put forward, in clinical trial methodology and interpretation of their results and in assessment criteria and Submission deadlines and Procedural timetables from the relevant health authorities is needed. Benchmark data on pricing and reimbursement for other products can be invaluable to gain expertise and understanding.

c) Clinical trial applications

In most organisations, the Regulatory affairs department is responsible for the submission, follow-up and update of clinical trial application to the competent authorities.

d) Labelling requirements

Regulatory affairs departments are responsible for ensuring compliance of the packaging materials of marketed products with the current regulations.

Thorough knowledge of regulations and guidelines includes

- labelling requirements,
- excipients in the Label and Package leaflet
- consultations with target patient groups for assessment of the readability of the package leaflet,
- QRD templates when relevant

e) Quality assurance and regulatory compliance

Regulatory affairs departments can be in charge of compliance and quality management systems for all the regulatory activities under its responsibilities.

Knowledge is needed in writing procedures, training the regulatory staff on the procedure and training the other department staffs to some cross-departmental procedures, when relevant performing self-inspection or audit.

f) Scientific information

According to the structure of the pharmaceutical company, regulatory affairs departments can be in charge of scientific information for all or part of the portfolio.

Knowledge is needed in the pre-clinical and clinical development, in the scientific data available on the concerned products and in the relevant therapeutic area.

g) Pharmacovigilance

Regulatory Affairs Department works in close collaboration with the Drug Safety department and the Qualified Person for Pharmacovigilance, in order to establish renewal and PSURs planning on a yearly basis for each product and collect all the information needed for their submission, also taking into consideration post-approval commitments or follow-up measures.

In some organisations, the Regulatory Affairs professional is also the Qualified Person for Pharmacovigilance (QPPV).

h) Communication, negotiation

Due to the multidisciplinary activities under the responsibility of the regulatory affairs department, close relationship with almost all the other departments (pre-clinical, medical, drug safety, pharmacovigilance, production, quality control, quality assurance, medical services, marketing and sales etc.) is needed and requires appropriate negotiating and project management soft skills.

Skills and knowledge for communication and communicating information to other departments, Competent Authorities, Professional Associations are a key parameter in terms of compliance with regulatory requirements, lobbying, negotiation and effective relationship with external bodies.

In addition, one of the major requisites of a regulatory affairs professional is his/her project management competence in organising a large number of different projects and tasks at the same time while ensuring the appropriate timing of the respective tasks according to the regulatory deadlines. Since the regulatory affairs professional depends on the input of the various disciplines within the company such as clinical, non-clinical, marketing etc., his communicational and administrative skills should be rather distinct.

Remarks: Many other knowledge elements might be requested according to the portfolio of the pharmaceutical company and the kind of regulatory activities performed by the relevant regulatory affairs department such as knowledge in compassionate use regulation, import/export regulation, paediatric regulation, Cell therapy and tissue engineering, Vaccines, Biosimilars, Gene Therapy, Pharmacogenomics, herbal medicinal products, OTC drugs etc.

F. Key Regulatory Competences

The following are key regulatory competences listed by The Organisation for Professionals in Regulatory Affairs (TOPRA) under Lifelong Learning and the list is made available on their website (http://www.topra.org/lifelong-learning).

1. Human Medicines: Regulatory Competences

1.1. Knowledge about the discovery and development of pharmaceutical products
1.2. Knowledge about emerging technologies for dosage form design, delivery systems
1.3. Knowledge and application of current procedures for obtaining approval to carry out clinical trials in the European Union (CTAs, IMPDs and other supporting documentation)
1.4. Knowledge and application of current procedures for obtaining approval in other countries as appropriate to carry out clinical trials
1.5. Knowledge and application of principles of Good Clinical Practice (GCP)
1.6. Knowledge and application of principles of Good Manufacturing Practice (GMP), the Qualified Person their legal duties and role
1.7. Knowledge and application of registration procedures in Europe (Centralised, Mutual Recognition, Decentralised) for MA approvals, variations, extensions and renewals
1.8. Knowledge and application of the registration procedures in other markets as appropriate for approvals, changes and updates
1.9. Knowledge and application of the technical, chemical, pharmaceutical and biological requirements for registration of chemical entities
1.10. Knowledge and application of the technical requirements for registration of biological and biotechnological products
1.11. Knowledge and application of the nonclinical requirements for registration of chemical, biological and biotechnological products
1.12. Knowledge and application of the clinical requirements for registration of chemical, biological and biotechnological products
1.13. Knowledge and application of the content and format of registration files (Common Technical Document and eCTD)
1.14. Knowledge and application of Pharmacovigilance and the qualified person
1.15. Knowledge and application of requirements for information for promotion, labelling (SPC, PIL, user acceptance testing, Braille labelling)
1.16. Knowledge and application of requirements for risk management (clinical, quality)
1.17. Knowledge and application of regulatory compliance with the approved registration file/change control
1.18. Knowledge and application of environmental risk assessment for human medicinal products
1.19. Knowledge and application of reimbursement and economic assessment (for prescribability)
1.20. Knowledge and application of advertising and promotional material clearance

2. Human Medicines: OTC Products

2.1. Knowledge and application of legislation for changing legal supply classification (e.g. prescription to pharmacy sale)
2.2. Knowledge and application of advertising and promotional material clearance

3. Medical Devices

3.1 Knowledge and application of the Medical Devices legislation (EU Directives) and guidelines (MEDDEVs), awareness of Global Harmonisation Task Force (GHTF) documents
3.2 Knowledge and application of emerging technologies for medical devices
3.3. Knowledge and application of Device Vigilance

4. Cosmetics and Borderline Products

4.1 Knowledge and application of the Cosmetics Directive (76/68/EC) and associated legislation
4.2 Knowledge and application of the borderline between Cosmetics, Medicines and Medical Devices

5. Chemicals

5.1 Knowledge and application of the new proposed EU regulatory framework for Registration, Evaluation and Authorisation of Chemicals (REACH), and the transition Research Implementation Projects (RIPs)

6. Food Additives

6.1 Knowledge and application of legislation and submissions for authorisation of additives permitted in foodstuffs

7. Pesticides and Biocides

7.1 Knowledge and application of requirements under 91/414/EEC (or as amended) The Plant Protection Products Directive and 98/8/EC (The Biocidal Products Directive) and how to apply them.

8. Veterinary Medicines: Key Regulatory Competences

8.1 Knowledge and application of principles of Good Laboratory Practice (GLP) and its application in clinical studies used in veterinary medicinal product applications
8.2 Knowledge and application of the requirements for veterinary feed additives for farm animals
8.3 Knowledge and application of the clinical requirements for veterinary medicinal products for large animals
8.4 Knowledge and application of the clinical requirements for veterinary medicinal products for companion animals
8.5 Knowledge and application of principles of Good Manufacturing Practice (GMP), the Qualified Person their legal duties and role
8.6 Knowledge and application of user safety requirements for veterinary products
8.7 Knowledge and application of environmental risk assessment of veterinary medicinal products
8.8 Knowledge and application of advertising and promotional material clearance

9. *Soft Skills*

9.1 Negotiation and influencing skills
9.2 Presentation skills for regulators

9.3 Team working in a global environment
9.4 Project management and strategic thinking
9.5 Time management
9.6 Leadership skills
9.7 Performance management
9.8 Marketing for regulators
9.9 Crisis management

10. ***IT Competences*** will include knowledge and application of:

10.1 Word processing,
10.2 Spreadsheets,
10.3 Presentations,
10.4 Project management,
10.5 Document Management Systems,
10.6 Publishing/eCTD etc

H. RA Degree and Certification Programmes

These degrees and certification programmes are advisable but not necessary for RA professional, and they will be different in each country.

REGULATORY AFFAIRS TRAINING COURSES

EUROPE

Rheinische Friedrich Wilhelm University, Bonn, Course in Regulatory Affairs
Applications to the German Society for Drug Regulatory Affairs:
Geschäftsstelle für Drug Regulatory Affairs
Schedestraße 9, D-53113 Bonn,
Tel. 0049-228-368264-6; Fax 00+49-228-368264-7.

SIR Institute for Pharmacy Practice and Policy, Leiden, European Regulatory Affairs Course
Course Organisers: For more information, please contact Mrs. T.M. Bakker-Krol , Dr H. Buurma or Prof. dr H.G.M. Leufkens.
SIR Institute for Pharmacy Practice and Policy
Theda Mansholtstraat 5b
2331 JE Leiden
The Netherlands
Phone +31 (0)71 5766157
Fax +31 (0)71 5722431
E-mail secretariaat@stevenshof. nl
Website www.stevenshof.nl

Medicademy, Denmark, Diploma in Regulatory Affairs, Masters in Regulatory Affairs
Contact: Medicademy,
P.O. Box 829
Strødamvej 50ª
DK-2100 Copenhagen Ø
Denmark
Telephone: +45 39 15 09 10
Telefax: +45 39 27 62 19
mail@medicademy.net

TOPRA, Diploma in Regulatory Affairs, M.Sc in Regulatory Affairs
.For further information and an application form please email mscadmin@topra.org

TOPRA
7 Heron Quays
Marsh Wall
London E14 4JB
United Kingdom
Tel: +44 (0) 20 7538 9502
Fax: +44 (0) 20 7515 7836

Drug Information Association. Various courses in Regulatory Affairs, Masters in Regulatory Affairs

DIA EUROPE
ELISABETHENANLAGE 25, POSTFACH,
4002 BASEL, SWITZERLAND
PHONE: +41 61 225 51 51 / FAX: +41 61 225 51 52
E-MAIL: DIAEUROPE@DIAEUROPE.ORG

WORLDWIDE HEADQUARTERS
800 ENTERPRISE ROAD, SUITE 200
HORSHAM, PA 19044-3595
PHONE: +1 215 442 6100 / FAX: +1 215 442 6199
E-MAIL: DIA@DIAHOME.ORG

USA

Campbell University School of Pharmacy**, Buies Creek, NC**
Bachelor of Science in Clinical Research (BSCR) and Master of Science in Clinical Research

Hood College, Frederick, MD
Certificate in Regulatory Compliance

Johns Hopkins University, Baltimore and Rockville, MD
Master of Science in Biotechnology with a concentration in Regulatory Affairs
Master of Science in Bioscience Regulatory Affairs

Keck Graduate Institute, Claremont, CA
Master of Bioscience (MBS) with emphasis in Clinical Regulatory Affairs

Lehigh University, Bethelem, PA
Certificate in Regulatory Affairs

Long Island University—Arnold and Marie Schwarzt College of Pharmacy, Brooklyn, NY
Master of Science with a specialization in drug regulatory affairs

Massachusetts College of Pharmacy, Boston, MA
Master of Science in Drug Regulatory Affairs and Health Policy

Northeastern University, School of Professional and Continuing Studies, Boston, MA
Master of Science in Regulatory Affairs
Graduate Certificate in Biopharmaceutical Domestic Regulatory Affairs
Graduate Certificate in Biopharmaceutical International Regulatory Affairs
Graduate Certificate in Clinical Trial Design and Project Management

Northwestern University School of Continuing Studies, Chicago, IL
Master of Science in Quality Assurance and Regulatory Science
Master of Science in Clinical Research and Regulatory Administration

Purdue University, West Lafayette, IN

Regulatory and Quality Compliance Graduate Certificate Program

Regis College, Weston, MA
Master of Science in Health Product Regulation
Gradate Certificate in Product Regulation or Clinical Research

San Diego State University, San Diego, CA (Center for Bio/Pharmaceutical and Biodevice Development)
Advanced Certificate in Regulatory Affairs and Master of Science in Regulatory Affairs

St. Cloud State University, St. Cloud, MN
Master of Science in Regulatory Affairs and Services, with focus on medical devices
http://www.stcloudstate.edu/RAS/

St. Johns University, New York, NY
Master's in pharmacy administration with a specialization in Pharmaceutical Marketing and Regulatory Affairs/Quality Assurance.
http://www.stjohns.edu/academics/graduate/pharmacy/departments/pas/ms_pa

Temple University, Philadelphia, PA
Master of Science in Quality Assurance/Regulatory Affairs and Post-Master's certificate in Advanced Quality Assurance or Regulatory Affairs

University of California, San Diego Extension, San Diego, CA
Certificate in Regulatory Affairs Essentials and Certificate in Regulatory affairs for the Biomedical Industry

University of California, Irvine Extension, Irvine, CA
Certificate in Medical Product Development
Certificate in Clinical Trials: Medical Device and Drug Development
Regulatory Affairs Essentials

University of California, Santa Cruz Extension in the Silicon Valley, Cupertino, CA
Regulatory Affairs Certificate Program (including drug and device tracks)
Clinical Trials Design and Management Certificate Program
www.ucsc-extension.edu/biosciences

University of Georgia, College of Pharmacy, Athens, GA
Master of Science in Pharmacy, emphasis in Regulatory Affairs
Graduate Certificate in Clinical Trial Design and Project Management
Graduate Certificate in Regulatory Affairs

University of Maryland, Baltimore County, Baltimore, MD
Post-Baccalaureate Certificate in Biochemical Regulatory Engineering

University of Rhode Island, Kingston, RI
MS/PhD Program in Pharmaceutics and Pharmacokinetics

University of Southern California, Los Angeles, CA
Master of Science in Regulatory Science
Certificate Program in Clinical Research Design and Management
Certificate Program in Patient and Product Safety

University of Washington Extension
Certificate Program in Biomedical Regulatory Affairs

University of Wisconsin-Madison, Department of Engineering Professional Development, Madison, WI
Regulatory affairs, quality assurance, pharmaceutical engineering.

Regulatory Affairs Professionals Society
Regulatory Affairs Certificate Courses – US, Europe, Canada

Contact: Regulatory Affairs Professionals Society (RAPS)
5635 Fishers Lane, Suite 550, Rockville, MD 20852
Phone: 1 301 770 2920 Fax: 1 301 770 2924
Email: raps@raps.org

Canada

Humber College, Toronto, Ontario
Regulatory Affairs Postgraduate Certificate

Seneca College, Toronto, Ontario
Pharmaceutical Regulatory Affairs and Quality Operations Graduate Certificate

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