

Pharmacovigilance Training and Education

PIPA Conference July 2006
“Expanding Our Horizons”

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Shire Pharmaceuticals



Outline

- Pharmacovigilance Training and Education
- Qualified Person for Pharmacovigilance
 - Inspections
- External course(s) *versus* in-house training
 - Computer-Based Training (demonstration)
- Ten years of the PIPA Postgraduate Course
- The future:
 - Distance learning & Scheme Reassessment



Training vs. Education

What is the difference –
is there a practical example?

























EU Qualified Person for Pharmacovigilance

Training & Education



EU Qualified Person for Pharmacovigilance

Volume 9A Role and Responsibilities - EU QPP

1.2 Roles and Responsibilities of the Marketing Authorisation Holder and the Qualified Person Responsible for Pharmacovigilance

The role of this Qualified Person is very important, and this Chapter therefore describes the role and responsibilities of the Qualified Person but also provides guidance for the Marketing Authorisation Holder on how to adequately support the Qualified Person.

The Qualified Person should be appropriately qualified. This means that he should have documented experience in all aspects of pharmacovigilance in order to fulfil his responsibilities and tasks. If he is not medically qualified, access to a medically qualified person should be available.

Volume 9A, Draft of 21Dec2005, p. 19, Lines 694 to 696 and 704 to 706.



EU Qualified Person for Pharmacovigilance

Volume 9A of the Rules Governing Medicinal Products in the European Union

1.2.1 The Role and Responsibilities of the Qualified Person Responsible for Pharmacovigilance

It is recognised that this important role of Qualified Person may impose extensive tasks on the Qualified Person, depending on the number and type of medicinal products for which the company holds authorisations. The Qualified Person may therefore assign specific tasks, under his supervision, to appropriately qualified and trained individuals, e.g. acting as safety experts for certain products, provided he maintains system oversight and overview over the safety profiles of all products. Such assignment needs to be documented.

Volume 9A, Draft of 21Dec2005, p. 20, Lines 719 to 724.



EU Qualified Person for Pharmacovigilance

EU QPP Role and Responsibilities - Training

1.2.1 The Role and Responsibilities of the Qualified Person Responsible for Pharmacovigilance

The oversight referred to above should cover the functioning of the Marketing Authorisation Holder's pharmacovigilance system in all aspects, including quality control and assurance procedures, standard operating procedures, database operations, compliance data (e.g. in relation to the quality, completeness and timeliness for expedited reporting and submission of Periodic Safety Update Reports), audit reports and training of personnel in relation to pharmacovigilance.

Volume 9A, Draft of 21Dec2005, p. 20, Lines 751 to 755.



EU Qualified Person for Pharmacovigilance

Volume 9A Evaluation of ICSRs - Assessment

1.3.4.a Evaluation of Individual Case Data

Following validation, evaluation of the case report includes determination of seriousness and expectedness of the adverse reaction. These terms (seriousness and expectedness) have specific meanings in the context of adverse reaction report evaluation (see Annex 1). Evaluation of the probability of the causal relationship between medicinal products and the reaction(s) is undertaken when considered appropriate. All methods used to evaluate these parameters should be documented. Evaluators should be trained in the methods used and their training verified.

Volume 9A, Draft of 21Dec2005, pp. 94-95, Lines 3179 to 3184.



EFPIA Position Paper - Role of EU QPP

Discharge of Responsibility

13. ...PV system...relies upon the performance of essential tasks by a number of individuals... ...QPPV may rely upon the performance of tasks and functions by **appropriately qualified and trained individuals.**

...QPPV may:

a) properly assign and/or delegate specific QPPV tasks and functions to **appropriately qualified and trained individuals** acting as deputies/alternate QPPVs

AND

b) may rely upon **experienced personnel** for the carrying out of general pharmacovigilance activities, provided that the **QPPV is satisfied that the persons and processes are capable of performing as required to a proper standard.**



Education and Risk



Mother-in-law hypothesis

Volume 9A: Risk Minimisation

3. TABLE: METHODS FOR RISK MINIMISATION

1. Risk Minimisation

Risk minimisation activities can be divided into those where a reduction in risk is achieved primarily through the provision of information and education and those which seek to control the use of the medicine. When it is obvious that a risk minimisation activity will be needed post authorisation, consideration should be given to piloting the activity during the development phase to see the effectiveness and suitability. When this is done, the outcome should be provided in the risk minimisation plan under the appropriate action.

1.1 Provision of Information

Provision of information to Healthcare Professionals and/or Patients on the specific risks of a product and the measures on how to reduce them is an essential activity of risk management. This provision of information may be confined to information contained within the Summary of Product Characteristics (SPC) and Package Leaflet (routine risk management) or may be through the use of additional educational material (additional risk management). The need for additional material beyond the Summary of Product Characteristics and Package Leaflet will depend upon the risk and should be considered on a case by case basis. Experts in risk communication should be consulted as appropriate.

Volume 9A: Education about risk

1.1.1 Additional Educational Material

The need for additional educational material and the form in which it should be provided will depend upon the specific safety concern. The aim of a specialised educational programme for healthcare professionals and/or patients is to:

- Enhance understanding of the specific risk(s)
- Enhance understanding of measures to reduce either the frequency or severity of adverse reactions
- Enhance early detection and treatment (if applicable) of an adverse reaction
- Enhance patient information, awareness and provide information on the need and use of additional precautions.

The educational programme may include but is not limited to the following materials:

- Direct Healthcare Professional Communications
- Physician's Guide to prescribing
- Pharmacist's Guide to dispensing
- Checklists for assessing comprehension, knowledge, attitudes, and/or desired safety behaviours about the risk(s). These should be tailored to the target audience (e.g. physicians, pharmacists or patients).
- Checklists for actions before prescribing or dispensing
- Patient information Brochures
- Specific training programmes.

Inspections – Training Records

The Qualified Person will act as the Marketing Authorisation Holder's contact point for pharmacovigilance inspections.

Volume 9A, Draft of 21Dec2005, pp. 21, Lines 756 and 757.

- EU QPP's CV is sent to all Member State Competent Authorities (where the Company is a MAH) and to the EMEA
- Individual PV staff training records may be reviewed by Inspectors and Auditors



External course(s)

versus

In-house training

Build or Buy?



External Courses

- Industry Expert Groups
 - PIPA (SIGAR), Drug Information Association, EFPIA, ABPI, TOPRA, BARQA, ACDM et al.
- Academic Institutions/NGOs
 - Universities of Hertfordshire, Cardiff, Surrey, City, London School of Hygiene & Tropical Medicine, St Bartholomew's Hospital
 - Drug Safety Research Unit, WHO Monitoring Centre
- Regulatory Agencies
 - MHRA, EMEA, FDA
- Commercial Organisations



In-House Training

- Inform colleagues of current developments (e.g. PV regulations and guidelines, signal detection, electronic reporting)
- Subject experts lead training and develop other members of the team
- Consultants recruited to supplement in-house expertise where gaps are identified

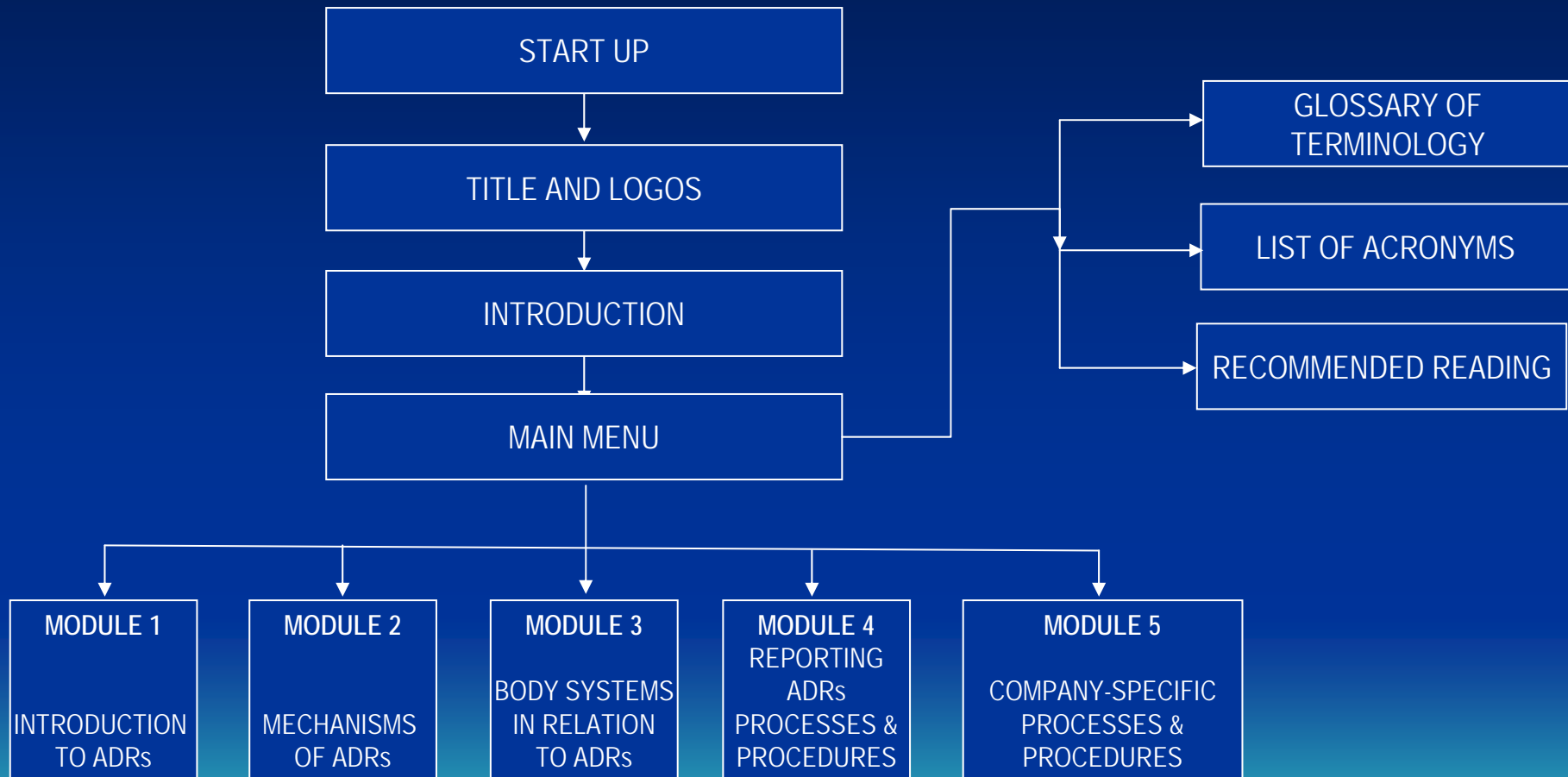


Computer-Based Training

- Discussion with commercial vendors
- Outline plan of training – Course Map
 - Start-Up screen and Menus
 - Titles and logos
 - Introduction
 - Main menu
- Modular design
 - Modules, Glossary, Acronyms & Hyperlinks



Course Map Pharmacovigilance CBT



CBT Demonstration

- User Manual and instructions
- Load program
- Overview of Modules
- Tests



Pitfalls for the unwary

- Be sure that your training consultant is clearly and precisely briefed
 - Outline topic and points of focus
 - Define scope and essential content
 - Agree a timeline and factor in acceptance testing
 - Set checks and conduct tests of knowledge
- If using in-house staff to lead training
 - Check appropriate accreditation or experience
 - Ensure the qualifications/skills are documented



Ten years of the PIPA Postgraduate Course

University of Hertfordshire



Course Start-Up

- Original proposal by SIGAR Chairperson
- Adopted by the 'SIGAR Six':
 - Jacquie Bomford (Bayer)
 - Iain Cockburn (Innovex)
 - David Lewis (SmithKline Beecham)
 - John Talbot (Glaxo Wellcome)
 - Margaret Walters (Merck, Sharpe & Dohme)
 - Louise Wood (MCA)



Communication: ABPI Medical Committee

DIPLOMA IN PHARMACOVIGILANCE

I think you have struck oil. Herewith the replies received to date, including a few queries for you to answer direct.

I will send you any further completed questionnaires as they arrive. Congratulations on fielding what looks like being a very successful initiative.

DIPLOMA IN PHARMACOVIGILANCE

Many thanks for your letter of 3 March with its enclosure. The members of the Medical & Scientific Information Committee are very pleased to know how successful this survey has been, and we wish the project well.

Best wishes

Yours sincerely



Dr Frank Wells

Director, Department of Medicine, Science and Technology

Host selection

- Selection criteria
 - University accreditation
 - Location (location, location)
 - Cost effectiveness
- Shortlist of four colleges:
Cardiff, Hertfordshire, Kingston, Nottingham
- Questionnaires and personal visits
- Final selection by the SIGAR Six



Stakeholder survey

PHARMACOEPIDEMOLOGY AND DRUG SAFETY, VOL. 4: 305–309 (1995)

EDUCATIONAL SURVEY

Pharmacovigilance Education and Certification Report on a Feasibility Survey

SIGAR*

SUMMARY

A survey conducted by the Special Interest Group on Adverse Reactions (SIGAR) identified an interest in developing a formal educational programme on pharmacovigilance. The majority of potential delegates had between 1 and 5 years of experience in pharmacovigilance and held higher qualifications. They were prepared to provide up to 6 hours of self-study per week but only a minority would sponsor themselves.

Managers envisaged providing at least one candidate for up to three modules per annum. Preferred modules included regulatory requirements and guidelines, spontaneous reporting, methodologies and company systems. As a result of this favourable response an academic partner has been appointed in the United Kingdom and the course will commence in 1996.

Number of staff and experience

Involved in pharmacovigilance = 324 (5.8 per manager response[‡])

Interest in a Certificate[§] = 73 (1.3 per manager response[‡])

Interest in a Diploma^{||} = 77 (1.4 per manager response[‡])

Areas of responsibility

	Managers	Potential delegates
United Kingdom	44 (79%)	30 (75%)
Europe	10 (18%)	10 (25%)
Worldwide	16 (29%)	9 (23%)

Accreditation

- Definitive Scheme Document (Sep-1995)

Pharmacovigilance

“A modular programme leading to named awards by part-time study”

- Eight Model Course Descriptions (MCDs)



Course Content

1. Principles of Pharmacovigilance
2. Adverse Drug Reactions by major body systems
3. Pharmacovigilance Regulations and Guidelines
4. Pre-Marketing Methodologies in Pharmacovigilance
5. Spontaneous Reporting of Adverse Drug Reactions
6. The Management of Drug Safety Data
7. Post-Marketing Methodologies in Pharmacovigilance
8. Causality Assessment, Ethics and Product Liability

MSc Project (Dissertation of 10,000 to 15,000 words)



Academic Review

Professor David Lawson CBE was:

“...impressed by the contents [of the Definitive Scheme Document] and the way the document is set out.”

“...very happy to endorse this course and congratulate you on all the work that has gone into its preparation... ...[and] on the wide spread of talent involved in the course.”



Publicity & Venue

Scrip 2076 10Nov1995

PgC, PgD and MSc Pharmacovigilance*

Flexible schemes designed with SIGAR to meet the needs of
Pharmacovigilance and Drug Safety Scientists;
Medical Information Scientists; Pharmaceutical Physicians;
Clinical Research Scientists and Drug Information Pharmacists.

Four 3 day courses per year, with introductory module
Principles of Pharmacovigilance on 5 - 7 February '96

For further information contact: Mrs T Arnold

Tel 01707 284503 Fax 01707 284514

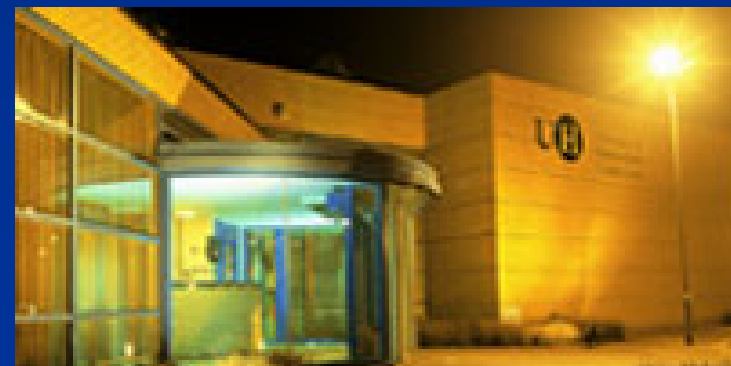
**subject to approval*



The University of Hertfordshire is a Registered Charity committed to the furtherance of education.



Fielder Centre, University of Hertfordshire



5-year review

The review panel comprised two external Heads/Deans of Faculty plus Jeff Aronson (External) and the Associate Dean of the Natural Sciences Faculty. The review involved a combination of closed meetings of the panel, interviews with past and present student representatives, discussion of questions with the Scheme Advisory Board and, finally, a verbal report back from the panel.

I am delighted to say that after some intensive questioning and thorough review of our work the panel are to recommend approval of the revised Postgraduate Scheme in Pharmacovigilance. A specific commendation was provided to all those involved in the development of the course because of the "high quality" of the content and presentation. The Chairman of the review panel remarked on how rarely he had been able to provide unconditional feedback, and went on to stipulate that there were no conditions, merely three recommendations. These are:

- A structured approach should be considered to (MSc) project development. [We can achieve this by setting a piece of coursework on drawing up a plan for an MSc Project - simple and effective!].
- There should be more systematic review of ADRs. [Largely achieved by the revised 8th module - but we should do more to steer the students towards large scale reviews and evaluation rather than single case assessments].
- The Scheme documents should adopt, in full, generic University regulations, or justify exemptions to the Pro-Vice Chancellor in writing.

I think we can be proud of what we have achieved and move forward with these caveats in mind.



Course Content 2001 (CIFs)

1. Principles of Pharmacovigilance
2. Adverse Drug Reactions by Major Body Systems
3. Pharmacovigilance Regulations and Guidelines
4. Pre-Marketing Methodologies in Pharmacovigilance
5. Spontaneous Reporting of Adverse Drug Reactions
6. Pharmacovigilance Data Management
7. Post-Marketing Methodologies in Pharmacovigilance
8. Labelling and Risk Management

MSc Project (Dissertation of 10,000 to 15,000 words)



Student Recruitment (UK/Non-UK)

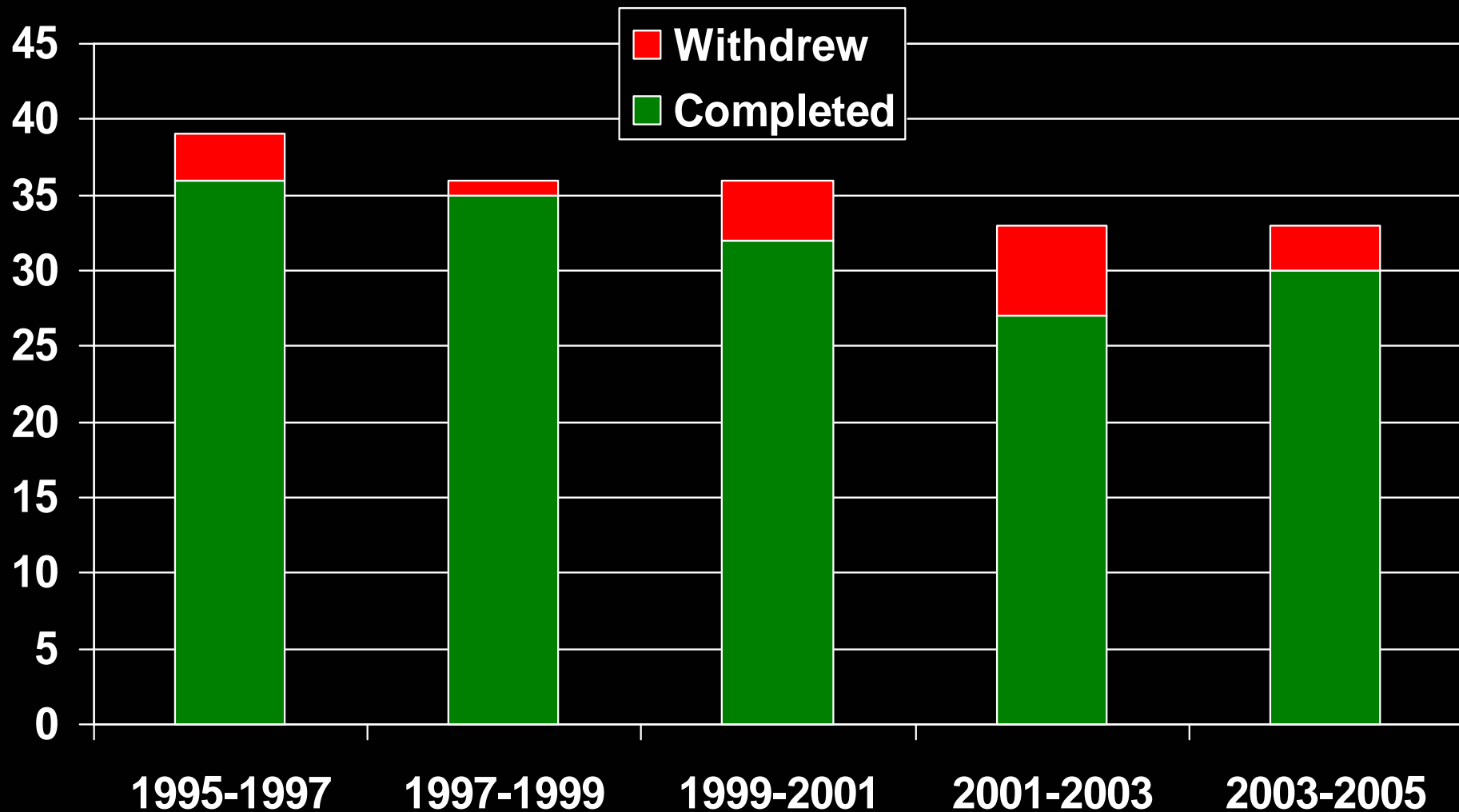
- UK students = 105
- **Non-UK = 55**
- **Belgium**
- **Denmark**
- **Germany**
- **Finland**
- **Ireland**
- **Japan**
- **Kosovo**
- **Netherlands**
- **Norway**
- **Portugal**
- **Slovenia**
- **Spain**
- **South Africa**
- **Switzerland**
- **USA**



Students' job titles

- Drug Safety Scientist, Product Safety Scientist, Drug Safety Associate, Pharmacovigilance Officer, Pharmacovigilance Executive, Clinical Safety Scientist, Medical Information Officer
- Safety and Pharmacovigilance Specialist, Senior Drug Safety Associate, Principal Safety Scientist
- Pharmacovigilance Manager, Drug Safety Manager, Product Safety Manager for Europe, Global Standards and Quality Assurance Manager
- Clinical Research Physician, Clinical Reviewer
- Pharmacovigilance Manager, Medical Information Manager, Drug Safety and Licensing Manager
- Head of Safety and Quality Assurance; Director, International Regulatory Affairs; Assistant Vice President, Pharmacovigilance

Pharmacovigilance programme data 1995-2005 {160 awards/177 enrolled (90.4%)}



Attainments by cohort

Cohort	PgCertificate	PgDiploma			MSc		
		Pass	Credit	Dist ⁿ	Pass	Credit	Dist ⁿ
95/97	7	5	16	4	-	1	1
97/99	5	5	15	3	-	-	2
99/01	5	6	12	3	-	2	4
01/03	4	2	12	8	-	-	2
03/05	11	-	6	7	-	-	-
Total	32	18	61	25		3	9

Note students who have achieved awards may continue study for a higher award.

SIGAR / PIPA PRIZEWINNERS

Year	Student
2001	Sandra Meyer
2002	Catherine de Whalley
2003	Natasa Mihajlovic-Gojkovic
2004	Bina Kramhoft Schack
2005	Kathleen Belknap and Margreet Ockhorst-Besijn



Masters of Science

Author	Product-based Dissertations
Jacqueline Akhurst 1998	The use of Lofexidine by Drug Dependency Units in the United Kingdom
Wendy Roberts 2000	Major Congenital Abnormalities in Offspring of Women Treated with Antiepileptic Drugs: A Review of the Literature
Deirdre Moran 2006	Analysis of the Withdrawal of Rofecoxib: Pharmacovigilance Implications
Author	Dissertations on Training and Education
Solveig Blomvik 2000	The effect of a Short Course in Pharmacovigilance on medical representatives ability to contribute to the Pharmacovigilance activities of a European Pharmaceutical Company
Mette Stie Kallesoe 2006	Distance Learning in Pharmacovigilance: Evaluating and Assessing a Tool for Distance Learning for, and by, Local Safety Officers in Ferring Affiliates

Masters of Science (2)

Author	System and Process-based Dissertations
Natasa Mihajlovic-Gojkovic 2002	Designing for Drug Safety in the EU – Associated Countries: Focus on the Pharmacovigilance system of the Bosnia and Herzegovina
Bina Kramhoft Schack 2004	Quality Management in Pharmacovigilance; Effect on Quality of Reports
Kathleen M Belknap 2005	Managing Pharmacovigilance Audits and Inspections
Margreet Ockhorst – Besijn 2005	The development of a signal detection and signal testing scheme for marketed medicinal products.
Andy Cochrane 2005	Pharmacovigilance in the Electronic Age: Revolution or Evolution?
Irene Rebollo 2006	Electronic Transmission of Periodic Safety Reports
Kevin Woodward 2006	Aspects of Veterinary Pharmacovigilance

Work In Progress for MSc (3)

PROJECT TITLE

Literature Identification and Management in Pharmacovigilance.

Risk Management in Clinical Trials.

How to successfully manage Pharmacovigilance within Licensing Agreements.

Pharmacovigilance of herbal remedies: The past and present (1962 to 2002) and the challenges of the future.

Investigation into how a causal relationship between a post-marketed medicinal product and a suspect adverse reaction is assessed and classified on an individual case basis within different pharmaceutical companies.

The Internal Review Process compared with the External Review Process.

An investigation of why obese patients do not remain on Xenical therapy long-term for maintenance of weight loss.

After Sales Service

- UH/SIGAR also provides Pharmacovigilance Update meetings
- Symposia are run those who have completed an award (PgC, PgD or MSc)
- Provide participants with:
 - Subject matter updates
 - Continued opportunities for networking
 - Meetings with regulators in an informal setting



10-year review

- Next review planned for 4Q2006
- Re-assessment of course content
 - Risk Management
 - Signal Detection including disproportionality
 - Labelling (SmPCs, PILs, Company Core Safety Information)
 - EU Qualified Person for Pharmacovigilance
 - Volume 9A, ICH M5, E2C(R1), E2B(R) etc.
- Volunteers being sought to contribute



Distance learning

- UH is working with a potential commercial partner to develop distance learning modules
- Target audience includes:
 - Pharmacovigilance staff in North America and further afield (China, Korea, Japan)
 - EU Office-based staff with limited capability to travel
- Resource and development costs to be determined



Conclusions

- A variety of courses and programmes are available: use your contacts to determine what is best suited to you - be selective
- The development of an accredited, University-based course has been an education, not least for the Course Leaders!
- Distance learning and CBT have limitations
- Full participation as a student or speaker provides career development opportunities
- Networking alone is worth the course fee!



Next steps... ...are always the most dangerous

