

UKRT CPD example

Activity

Title of Activity:

Current Trends and Advances in Developmental and Reproductive Toxicology Testing

Venue:

Webinar

Description of activity:

This webinar topics included : Inclusion of Women of Childbearing Potential in Clinical Trials.; Minipig Embryo-Fetal Development Studies and pre-clinical juvenile study designs.

Outcome:

Learned how to support inclusion of Women of Childbearing Potential (WOCBP) in clinical trials. Regional differences were discussed along with use of non-traditional species (e.g. the minipig) in embryo-fetal studies

Notes:

Date of activity start/end: January 12, 2012

Number of credits claimed: 1

Additional evidence:

Category: General Interest Academic Professional

Activity

Title of Activity:

Planning and Understanding IND Programs

Venue:

Webinar

Description of activity:

This webinar topics included: What is an IND, types of IND, the drug development process, key regulatory guidelines, key preclinical studies to be included, planning of the program, missteps to avoid, and application of 3Rs.

Outcome:

Learned that every IND programme is unique and how an IND can be designed. Importance of using relevant (pharmacologically) active species and how to carefully correlate PK and PD.

Notes:

Date of activity start/end: January 17, 2012

Number of credits claimed: 1

Additional evidence:

Category: General Interest Academic Professional

Activity

Title of Activity:

The Role of Juvenile Animal Studies to Support Pediatric Drug Development

Venue:

Webinar

Description of activity:

The webinar topics included: when are juvenile studies needed, how to design juvenile toxicology studies, what species to use, number of species, timing of juvenile studies and regulatory interactions.

Outcome:

Learned that juvenile toxicity studies are big studies and should only be conducted if strictly needed (e.g inclusion of paediatrics). Good idea to discuss design with regulators before initiation of study. Very difficult to dose and bleed small juvenile animals and special skills are needed.

Notes:

Date of activity start/end: April 4, 2012

Number of credits claimed: 1

Additional evidence:

Category: General Interest Academic Professional

Activity

Title of Activity:

Webinar: The New ICH S2(R1) Genotoxicity Guideline

Venue:

Webinar

Description of activity:

Topics discussed in this webinar were 1) The requirement to score more cells for in vivo micronucleus studies, 2) Acceptance of rat blood for simpler integration into general toxicology studies and 3) The new role for in vitro micronucleus testing.

Outcome:

I gained an understanding of some of the important changes to these ICH regulations on genotoxicity testing and pharmaceutical safety assessment and learned how these modifications may impact our genotoxicity studies.

Notes:

Date of activity start/end: May 9, 2012

Number of credits claimed: 1

Additional evidence:

Category: General Interest Academic Professional

Activity

Title of Activity:

Genotoxicity Testing Strategies

Venue:

Webinar

Description of activity:

This Harlan webinar talked about the possible impact of the newly revised ICH S2(R1) Guideline on Genotoxicity testing strategies and data interpretation of Pharmaceuticals for Chemicals and Agrochemicals.

Outcome:

I gained an understanding of some of the important changes to these ICH regulations on genotoxicity testing and pharmaceutical safety assessment and learned how these modifications may impact our genotoxicity studies.

Notes:

Date of activity start/end: June 14, 2012

Number of credits claimed: 1

Additional evidence:

Category: General Interest Academic Professional

Activity

Title of Activity:

ICH S7B Guidelines: Then and Now

Venue:

Webinar

Description of activity:

This webinar was about the non-clinical testing strategy for assessing the potential of a test substance to delay ventricular repolarization. What assays can be used for screening and for regulatory purposes.

Outcome:

I learned that QT prolongation can seriously damage your drug (candidate) although it may not necessarily kill your drug provided a sufficient safety margin can be generated. Many in vitro screenings assays are available but ultimately a human TQT study is needed.

Notes:

Date of activity start/end: June 28, 2012

Number of credits claimed: 1

Additional evidence:

Category: General Interest Academic Professional

Activity

Title of Activity:

An Introduction to Drug Impurity Risk Assessment

Venue:

Webinar

Description of activity:

Topics discussed in this webinar were: how and when to qualification of impurities I drug substances and drug products. How to deal with genotoxic impurities and relevant guidelines

Outcome:

Very nice examples of genotoxic impurities were presented and how the TTC (threshold of toxicological concern) can be applied. In silico Structure-Activity Relationship models for mutagenicity prediction is a very important tool.

Notes:

Date of activity start/end: September 20, 2012

Number of credits claimed: 1

Risk/benefit can be highly subjective!!!!



Activity

Title of Activity:

Immunology in pharmaceutical safety assessment

Venue:

(Own Employer)

Description of activity:

I organized a 2 day intermediate immunology course with special emphasis on immunological safety evaluation of medicines. *** & *** from *** were guest speakers.

Outcome:

The purpose of the course was to strengthen the company's competences in this field as most of our projects are directed against the immune system. Immunotoxicology is a safety area of growing concern: regulatory bodies throughout the world increasingly require the immunotoxic potential of medicines and biologics as well as chemicals to be evaluated preclinically and clinically.

Notes:

Date of activity start/end: January 30-21, 2012

Number of credits claimed: 12

Additional evidence:

Category: General Interest Academic Professional

Activity

Title of Activity:

Society of Toxicology 51st Annual Meeting

Venue:

San Francisco, CA

Description of activity:

3.5 full days with poster session, workshops sessions, platform sessions and symposia sessions. Attended two 4 hour courses: Innate Immunity and its Relevance to Toxicology and Cutaneous Toxicity.

Outcome:

Very useful meeting. A lot of new science is presented and is also a great opportunity for networking, meeting with CROs, collaborators and colleagues. Learned a lot WRT immune system especially in the skin

Notes:

Date of activity start/end: June 28, 2012

Number of credits claimed: 15

Additional evidence:

Category: General Interest Academic Professional

Activity

Title of Activity:

Workshop on Metabolites in Safety Testing - are your drug metabolites safe?

Venue:

Stockholm, Sweden

Description of activity:

The workshop is a multi-disciplinary learning opportunity for participants from all perspectives: that the industry or academic scientist learns more about the regulatory guidances in this area; that the regulatory experts learn more about how their guidelines are interpreted in practice.

Outcome:

The safety of metabolites of drugs, in addition to the safety of the drug itself, must be established before a drug is considered for approval by regulatory agencies. Each species has the potential to generate unique or disproportionate amounts of drug metabolites and sometimes separate studies with metabolites are needed.

Notes:

Date of activity start/end: October 12, 2012

Number of credits claimed: 8

Additional evidence:

Category: General Interest Academic Professional

Activity

Title of Activity:

American College of Toxicology 33rd Annual Meeting

Venue:

Orlando, Florida, US

Description of activity:

3.5 full days with poster session, workshops sessions, platform sessions and symposia sessions. Attended a 4 hour course: Genetic Toxicology: Revised Guidelines (ACT 2012)

Outcome:

Very useful meeting. A lot of new science is presented and is also a great opportunity for networking, meeting with CROs, collaborators and colleagues. Learned a lot WRT genotoxicity and at revised testing strategy

Notes:

Date of activity start/end: November 4 - 7, 2012.

Number of credits claimed: 15

Additional evidence:

Category: General Interest Academic Professional

Activity

Title of Activity:

Speaker at Medicademy Modules 5 and 7
Speaker at MIND

Venue:

Copenhagen, Denmark

Description of activity:

Medicademy (A Diploma and Qualifying Education). Module 7: Non-clinical Development and Documentation.

Medicademy (A Diploma and Qualifying Education). Module 5: Preclinical and Clinical Aspects of Pharmacovigilance.

Speaker at MIND. Course on Non-Clinical Safety and Toxicology. Carcinogenicity testing of drugs

Outcome:

I enjoy teaching postgraduate students and it is also a great opportunity if you wish to develop your own scientific and teaching skills.

Notes:

Date of activity start/end: Feb 29 - March 2, 2012, May 8-10, 2012 and May 9, 2012

Number of credits claimed: 3

Additional evidence:

Category: General Interest Academic Professional

Activity

Title of Activity:

Reading of various journals with focus on xxx and immunology
Reading of various books and paper with focus on tumor promotors
Reading of various books and paper with focus on xxx inhibitors

Venue:

Copenhagen, Denmark

Description of activity:

My employer initiated 3 new projects in 2012 in order to help patients with skin diseases. Their targets were completely new to me and I had to study various papers and text books in order to become familiar with the targets and potential toxicity. The list of papers read is quit comprehensive and to exemplify I have just included some of my Cathepsin S papers on the next page. I receive Tocs for many journals on a daily/weekly basis. On a regular basis I read the following journals:

Journal of Applied Toxicology, American Journal of Pharmacology and Toxicology, International Journal of Toxicology, Expert Opinion on Therapeutic Targets, Expert Opinion on Drug Discovery, Expert Opinion on Investigational Drugs, Mutation Research/Genetic Toxicology and Environmental Mutagenesis, Journal of Pharmacological and Toxicological Methods, Reproductive Toxicology, Toxicology, Regulatory Toxicology and Pharmacology, Toxicology Letters, Toxicology Research, Toxicology and Applied Pharmacology, Critical Reviews in Toxicology, Journal of Pharmacology and Experimental Therapeutics, Toxicologic Pathology, Expert Opinion on Drug Metabolism & Toxicology, Expert Opinion on Drug Safety, Expert Opinion on Emerging Drugs, Toxicological sciences

WRT text books I have most of the key toxicology books available: see pics of "my library"




































Date of activity start/end: 2012

Number of credits claimed: 30

Additional evidence:

Category: General Interest Academic Professional



 13543776.2011	(
 Boceprevir phase I studies_FDA	(
 Boceprevir	2
 CAGLIC_Proinflammatory_cytokines_IL_1a and TNFa_promote_expression_and_secretion_of_proteolytically_active_c...	2
 CAi 2010_Merck ketoamide-based cathepsin S inhibitors	1
 Cathepsin S a new pruritus biomarker	(
 Cathepsin s and mortality in older adults	2
 Cathepsin S inhibitor prevents autoantigen presentation	1
 Cathepsin S Required for Normal MHC Class II	2
 Chemical biology of antigen presentation by MHC molecules	2
 Clark 2011_Cathepsin S fractalkine microglial signaling neuropathic pain	1
 Conus 2010_Involvement of cathepsins in immune responses	(
 CurrPharmDes2007	1
 Drug Metab Dispos-2011-Ghosal-510-21_enzyme reaction phenotyping of Boceprevir	1
 Effects of Hepatic Drug-metabolizing Enzyme Induction on Clinical Pathology Parameters	2
 Exploration of cathepsinSinhibitorscharacterized by atriazoleP1-P2amidereplacement	3
 Gupta 2008_Expert opinion cathepsin S inhibitors	(
 ICH M3(r2)	2
 Jobs Cat S JAMA 2011	(
 Löser 2011_Expert opinion Medivir cathepsin S patent	(
 pjab-87-029	(
 ProQuest-Alert_4-Documents_132426_AABNUT_accountid-132304_20120610_1800	1
 Reddy 2010_Cathepsin S itch protease-activated receptors	(
 Rudensky 2006_Cathepsin S MHC II antigen presentation review	1
 Sercarz 2003_MHC guided processing antigen invariant chain cathepsin	(
 Spinal Cathepsin S and Fractalkine Contribute to Chronic Pain	1
 The lysosomal cysteine proteases in MHC class II antigen presentation	2
 The PK evaluation of boceprevir for treatment of Hepatitic C virus	1
 The Significance of Hepatic Microsomal Enzyme Induction and Altered Thyroid Function in R	(
 Therapeutic dosing of an orally active selective cathepsin S inhibitor suppresses disease in models of autoimmunity	1
 Thurmond 2005_Cathepsin S inhibitors as novel immunomodulators	1
 Upregulation of cathepsin S in psoriatic keratinocytes	2
 Veilleux 2010_Probing of cathepsin S activity in whole blood	1
 Wiener 2010_Recent Advances in the Design of Cathepsin S Inhibitors	(
 Active cathepsins B, L, and S in murine and human pancreatitis	(

Snip of my Cathepsin S literature

Activity

Title of Activity:

Mini-pig Use in Safety Assessments During Drug Development
Rabbit as a Second Species: Future Designs of Development and Reproductive Tox (DART) Evaluations
Keeping Children Safe: Challenges of Nonclinical Juvenile Toxicology in Pediatric Drug Development
Practical Nanotoxicology
Practical Considerations in Large Molecule Drug Development

Venue:

Webinars

Description of activity:

These webinars were all relevant to my current job. The minipig is an excellent non-rodent alternative to dogs and monkeys in toxicology studies but not used a lot even though it may better predict human toxicity than other species. Juvenile toxicity is often requested by regulators although the value of these studies is being questioned as unique juvenile toxicity is very seldom. Nanotoxicology is a relatively new discipline which is of interest to my employer as new skin products may contain nanoparticles. Large molecules (Mabs) are very challenging from a toxicology point of view and studies must be designed carefully with inclusion of relevant PD markers to make sure the species chosen is relevant and pharmacologically responsive.

Date of activity start/end: February 27, October 24, December 4 and December 17, 2013

Number of credits claimed: 5

Additional evidence:

Category: General Interest Academic Professional

Activity

Title of Activity:

Society of Toxicology 52nd Annual Meeting

Venue:

San Antonio, Texas

Description of activity:

3.5 full days with poster session, workshops sessions, platform sessions and symposia sessions. Attended a 4 hour course: The What, When, and How of Nonclinical Support for an IND Submission.

Outcome:

Very useful meeting. A lot of new science is presented and is also a great opportunity for networking, meeting with CROs, collaborators and colleagues. Learned a lot WRT IND compilation and what to include and not to include in an IND, and what may put your clinical study on hold

Notes:

Date of activity start/end: March 10–14, 2013

Number of credits claimed: 15

Additional evidence:

Category: General Interest Academic Professional

Activity

Title of Activity:

Eurotox 2013, 49th Congress of the European Societies of Toxicology

Venue:

Interlaken, Switzerland

Description of activity:

3 full days with poster session, workshops sessions, platform sessions and symposia sessions.

Outcome:

Very useful meeting. A lot of new science is presented and is also a great opportunity for networking, meeting with CROs, collaborators and colleagues. The meeting was very useful for the pharma industry as Novartis and Roche (both located in Switzerland) gave excellent

Notes:

Date of activity start/end: March 10–14, 2013

Number of credits claimed: 12

Additional evidence:

Category: General Interest Academic Professional

Activity

Title of Activity:

Speaker (Minipig symposium). Species selection in drug development – the Göttingen Minipig
Speaker at Medicademy

Venue:

Copenhagen

Description of activity:

I enjoy teaching postgraduate students and it is also a great opportunity if you wish to develop your own scientific and teaching skills

I have used minipigs in ca 10 toxicology studies and I presented these cases to the audience and focused on how the minipig differ from dogs and monkeys and why it may better predict human toxicity than other species.

Date of activity start/end: May 29, 2013 and Nov 11-13, 2013

Number of credits claimed: 2

Additional evidence:

Category: General Interest Academic Professional



Picture of minipig (is actually smaller than a micropig)

Activity

Title of Activity:

Reading of various journals with focus on xxx antagonists
Reading of various book and papers with focus the non-human primate in non-clinical development

Venue:

Copenhagen, Denmark

Description of activity:

My employer initiated new projects in 2013 in order to help patients with skin diseases. Their targets were completely new to me and I had to study various papers and text books in order to become familiar with the targets and potential toxicity. XXX is a potential "pruritus" target and can potentially be used to treat patients with atopic dermatitis. The list of papers read is quit comprehensive. I receive Tocs for many journals on a daily/weekly basis. On a regularly basis I read the following journals:

Journal of Applied Toxicology, American Journal of Pharmacology and Toxicology, International Journal of Toxicology, Expert Opinion on Therapeutic Targets, Expert Opinion on Drug Discovery, Expert Opinion on Investigational Drugs, Mutation Research/Genetic Toxicology and Environmental Mutagenesis, Journal of Pharmacological and Toxicological Methods, Reproductive Toxicology, Toxicology, Regulatory Toxicology and Pharmacology, Toxicology Letters, Toxicology Research, Toxicology and Applied Pharmacology, Critical Reviews in Toxicology, Journal of Pharmacology and Experimental Therapeutics, Toxicologic Pathology, Expert Opinion on Drug Metabolism & Toxicology, Expert Opinion on Drug Safety, Expert Opinion on Emerging Drugs, Toxicological sciences

Date of activity start/end: 2013

Number of credits claimed: 30



Kid with AD

Activity

Title of Activity:

Critical perspectives on Flow Cytometry in Toxicology studies
Fundamental Approaches to Immunotoxicity Assessment in Preclinical Safety Studies
The impact of drug-related QT prolongation on FDA regulatory decisions
Safety Testing of Metabolites
Reproductive and Developmental Nonclinical Toxicity Testing
An introduction to the safety assessment of Biologics
Comparative Placental Transfer of Biologics: Preclinical Alternatives to the Nonhuman Primate
No Two are Ever the Same: Approaches to the Nonclinical Safety Assessment of Biologics
Perspectives on the Guidance for Industry: Immunogenicity Assessment for Therapeutic Protein Products

Venue:

Webinars

Description of activity:

These webinars were all relevant to my current job. Many of the webinars focused on the non-clinical development of monoclonal antibodies (Mabs) as these types of drug have shown excellent results in skin diseases – especially psoriasis. My employer has historically only worked with small molecules and it is hence very important for me to become familiar with preclinical drug development and toxicity testing of Mabs. Conducting Embryo-fetal development studies in non human primates is very challenging and requires very specific skills.

Date of activity start/end: January 14, February 12, February 27, May 21, September 10, September 24, October 21 and November 11, 2014

Number of credits claimed: 9

Additional evidence:

Category: General Interest Academic Professional

Activity

Title of Activity:

Society of Toxicology. 53rd Annual Meeting

Venue:

Phoenix, Arizona

Description of activity:

3.5 full days with poster session, workshops sessions, platform sessions and symposia sessions. Attended two 4 hour courses: Nonclinical Pediatric Drug Development: Considerations, Study Designs, and Strategies and Nonclinical Animal Models Enabling Biopharmaceutical Advances in Translational Medicine.

Outcome:

Very useful meeting. A lot of new science is presented and is also a great opportunity for networking, meeting with CROs, collaborators and colleagues. Learned a lot WRT juvenile toxicity testing and when and how to conduct these studies.

Date of activity start/end: March 23–37, 2014

Number of credits claimed: 15

Additional evidence:

Category: General Interest Academic Professional

Activity

Title of Activity:

Seminar on ICH M7 Guidance on Assessment of Impurities in Pharmaceutical Products

Venue:

Copenhagen

Description of activity:

The guidelines permit the use of genotoxicity QSAR models to replace actual testing. The guidelines state that a QSAR statistical-based methodology and expert alerts system can be used to predict the outcome of a bacterial mutagenicity assay to support hazard assessment.

Outcome:

Very useful meeting. My employer has subsequently acquired a QSAR system which may predict human and animal toxicities. This is very relevant to the pharma industry and may reduce the number of animals used

Notes:

Date of activity start/end: April 23, 2014

Number of credits claimed: 5

Additional evidence:

Category: General Interest Academic Professional

Activity

Title of Activity:

The 29th Annual Meeting of the BSTP held jointly with the ACCP and the MRF: Rational Selection of the non-rodent species.

Venue:

UK, Alderley Park

Description of activity:

Topics included: species selection in toxicology studies, use of minipigs, drug metabolism in non-rodent species, in vitro predictive toxicology, novel biomarkers, unusual findings and much more...

Outcome:

Very useful meeting. A lot of new science is presented and is also a great opportunity for networking, meeting with CROs, collaborators and colleagues. Learned a lot WRT use of minipigs in toxicology studies and how you justify your choice of non-rodent species e.g. based

Notes:

Date of activity start/end: April 23, 2014

Number of credits claimed: 8

Additional evidence:

Category: General Interest Academic Professional

Activity

Title of Activity:

Speaker at MIND. Master of Industrial Drug Development (MIND). Course on Non-Clinical Safety and Toxicology

Speaker at Medicademy (A Diploma and Qualifying Education). Module 5: Preclinical and Clinical Aspects of Pharmacovigilance

Venue:

Copenhagen

Description of activity:

I enjoy teaching postgraduate students and it is also a great opportunity if you wish to develop your own scientific and teaching skills

I teach carcinogenicity testing. When are carc studies need, how do you design carc studies? What are the values of such labor intense and expensive studies? What will carc testing look like in the future? Use of transgenic animals etc.

Date of activity start/end: Feb 25-27 May 7, 2014

Number of credits claimed: 2

Additional evidence:

Category: General Interest Academic Professional



Activity

Title of Activity:

Reading of various book and papers with focus on biologics for the treatment of skin diseases

Biopharmaceuticals drug development and preclinical safety evaluation of biopharmaceuticals

Venue:

Copenhagen, Denmark

Description of activity:

My employer has historically only worked with small molecules but in 2014 decided to start developing biologics (monoclonal antibodies) for the treatment of inflammatory skin diseases. In order to become familiar with preclinical drug development and toxicity testing of Mabs I read 2 key text books

1: *preclinical safety evaluation of biopharmaceuticals by Joy A Cavagnaro*

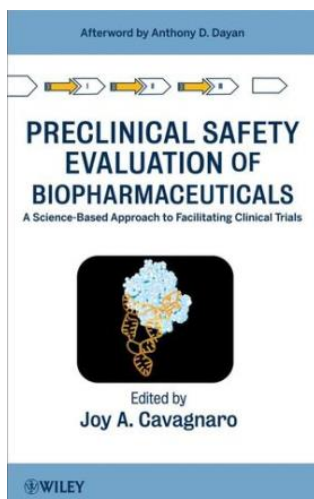
2: *The nonhuman primate in nonclinical drug development and safety assessment*

The list of papers read is quite comprehensive. I receive Tocs for many journals on a daily/weekly basis. On a regularly basis I read the following journals:

Journal of Applied Toxicology, American Journal of Pharmacology and Toxicology, International Journal of Toxicology, Expert Opinion on Therapeutic Targets, Expert Opinion on Drug Discovery, Expert Opinion on Investigational Drugs, Mutation Research/Genetic Toxicology and Environmental Mutagenesis, Journal of Pharmacological and Toxicological Methods, Reproductive Toxicology, Toxicology, Regulatory Toxicology and Pharmacology, Toxicology Letters, Toxicology Research, Toxicology and Applied Pharmacology, Critical Reviews in Toxicology, Journal of Pharmacology and Experimental Therapeutics, Toxicologic Pathology, Expert Opinion on Drug Metabolism & Toxicology, Expert Opinion on Drug Safety, Expert Opinion on Emerging Drugs, Toxicological sciences

Date of activity start/end: 2013

Number of credits claimed: 30



My favorite "biologics text book"

Activity

Title of Activity:

Juvenile Animal Studies: Regulatory and Industry Perspectives
Contemporary Concepts in Toxicology (CCT)
SEND -- What Can I Expect?
Impact of OECD Guidelines on Histopathology Peer Review

Venue:

Webinars

Description of activity:

These webinars were all relevant to my current job. Two of the webinars focused on SEND: The SEND format enables more efficient review of nonclinical data, offering improved data quality, accessibility and predictability. The standard itself has been designed to provide a vehicle for more easily transporting to regulators the results of the majority of standard regulatory toxicology studies.

The introduction of SEND for both regulatory submission and the electronic exchange of toxicology data is having a significant impact on the industry. My employer has bought new software and is hopefully ready to send SEND files to relevant authorities

Date of activity start/end:

January 28, May 18, December 8 and December 16, 2015

Number of credits claimed: 4

Additional evidence:

Category: General Interest Academic Professional

Activity

Title of Activity:

5th Annual Biologics Symposium
6th Annual Biologics Symposium

Venue:

London, UK

Description of activity:

The Annual Biologics Symposia (ABS) has been a successful part of the Envigo (UC based CRO) calendar since 2011. Focus was on immune oncology, autoimmune diseases and respiratory diseases. I learned about the latest strategies, data and insights that have really made a difference. Practical, case study based presentations were presented. An open networking forum for all attendees leading to thought-provoking and stimulating discussions.

Date of activity start/end: 2014

Number of credits claimed: 25

Additional evidence:

Category: General Interest Academic Professional

Activity

Title of Activity:

Society of Toxicology. 54th Annual Meeting

Venue:

San Diego, California

Description of activity:

3.5 full days with poster session, workshops sessions, platform sessions and symposia sessions. Attended two 4 hour courses: Toxicology and Regulatory Considerations for Combination Products and Interpretation of Cardiovascular Safety Data in Toxicology Studies

Outcome:

Very useful meeting. A lot of new science is presented and is also a great opportunity for networking, meeting with CROs, collaborators and colleagues. Learned a lot WRT combination products and how toxicity studies with combos can be designed.

Notes:

Date of activity start/end: March 22–36, 2015

Number of credits claimed: 15

Additional evidence:

Category: General Interest Academic Professional

Activity

Title of Activity:

Biopharmaceutical Training: Developing Monoclonal Antibodies (Covance)

Venue:

Copenhagen, Denmark

Description of activity:

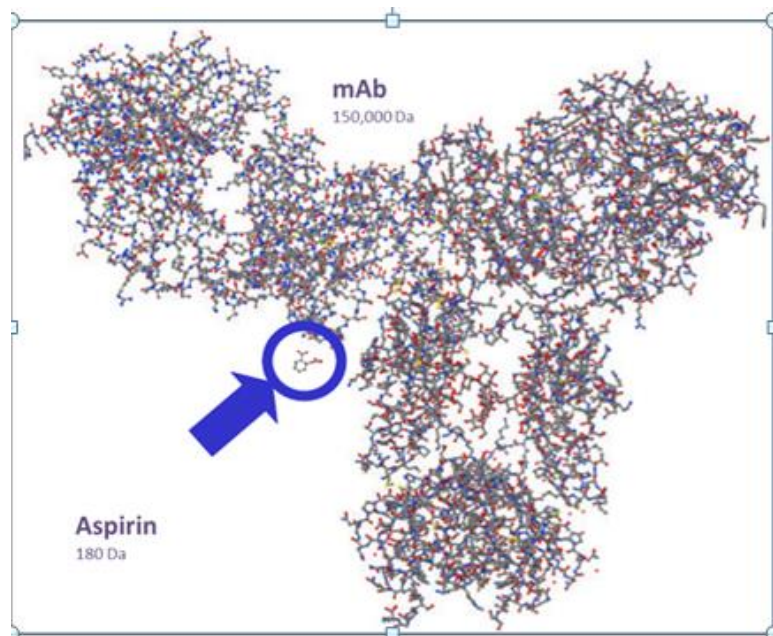
This was a full day biopharmaceutical course designed specifically for my employer's needs. Topics were: Non-clinical Development for Mabs and specific points for consideration for Mab X. Which studies are needed, when and what are the critical elements with regard to study design. First time in human studies with Mabs. The important pre-clinical data to enable the FTIH study. Bioanalytical testing for Monoclonals
This was of great relevance and value to our R&D since Mabs are now high on the company's agenda.

Date of activity start/end: September 16, 2015

Number of credits claimed: 5

Additional evidence:

Category: General Interest Academic Professional



Biologics are BIG...

Activity

Title of Activity:

Co-author of a published paper

Venue:

Copenhagen, Denmark

Description of activity:

Vehicle Systems and Excipients Used in Minipig Drug Development Studies. Weaver ML, Grossi AB, Schützsack J et al. Toxicol Pathol.

By presenting these data for dermal, oral, subcutaneous, and intravenous routes of administration, studies to qualify these vehicles in minipigs can be minimized or avoided. Additionally, investigators may more frequently consider using the minipig in place of higher species if the tolerability of a vehicle in the minipig is known

<http://journals.sagepub.com/doi/full/10.1177/0192623315613088>

Date of activity start/end: Dec 16, 2015.

Number of credits claimed: 2

Additional evidence:

Category: General Interest Academic Professional

Activity

Title of Activity:

Reading of various journals, book and papers with focus on yyy inhibitors for the treatment of inflammatory skin diseases

Company expanded into biologics necessary to implement new skill regarding preclinical safety evaluation of biopharmaceuticals

Venue:

Copenhagen, Denmark

Description of activity:

My employer initiated new projects in 2015 in order to help patients with skin diseases. Their targets were completely new to me and I had to study various papers and text books in order to become familiar with the targets and potential toxicity. YYY inhibitors are very promising drug candidates and several are being developed t for atopic dermatitis and psoriasis. However, many of the compounds demonstrate tricky toxicity and mechanistic /follow-up studies are needed. The list of papers read is quit comprehensive. I receive Tocs for many journals on a daily/weekly basis. On a regularly basis I read the following journals:

Journal of Applied Toxicology, American Journal of Pharmacology and Toxicology, International Journal of Toxicology, Expert Opinion on Therapeutic Targets, Expert Opinion on Drug Discovery, Expert Opinion on Investigational Drugs, Mutation Research/Genetic Toxicology and Environmental Mutagenesis, Journal of Pharmacological and Toxicological Methods, Reproductive Toxicology, Toxicology, Regulatory Toxicology and Pharmacology, Toxicology Letters, Toxicology Research, Toxicology and Applied Pharmacology, Critical Reviews in Toxicology, Journal of Pharmacology and Experimental Therapeutics, Toxicologic Pathology, Expert Opinion on Drug Metabolism & Toxicology, Expert Opinion on Drug Safety, Expert Opinion on Emerging Drugs, Toxicological sciences

WRT to biologics "*preclinical safety evaluation of biopharmaceuticals by Joy A Cavagnaro*" is my "bible".

Date of activity start/end: 2015

Number of credits claimed: 25

Additional evidence:

Category: General Interest Academic Professional

Activity

Title of Activity:

Impurities: The Good, the Bad, and the Ugly
SOT Drug Discovery Toxicology Specialty Section
Regulatory and Scientific Challenges in Biosimilar Development: Nonclinical Considerations
Carcinogenicity Assessment: Insights from Testing and Regulatory Review
Adversity in Nonclinical Reporting: Myths, Legends, and Reality
In Vivo Dermal Models for Drug Screening

Venue:

Webinars

Description of activity:

These webinars were all relevant to my current job. Three of the Webinars (impurities, adversity and carcinogenicity) were particularly relevant to me as these are challenges I deal with on a nearly daily basis. Carcinogenicity is very dear to me heart (and I also teach this discipline) and I'm eagerly aviating the new carcinogenicity testing strategy and revised guideline which hopefully will lead to a reduction in the number of future carc studies.

The introduction of SEND for both regulatory submission and the electronic exchange of toxicology data is having a significant impact on the industry. My employer has bought new software and is hopefully ready to send SEND files to relevant authorities

Date of activity start/end:

February 3, February 15, April 27, September 15, October 26 and November 29, 2016

Number of credits claimed: 6**Additional evidence:**

Category: General Interest Academic Professional

Activity

Title of Activity:

Society of Toxicology. 55th Annual Meeting

Venue:

New Orleans, Louisiana

Description of activity:

3.5 full days with poster session, workshops sessions, platform sessions and symposia sessions. Attended two 4 hour courses: Unique Approaches to Safety Assessment of Gene, Cell, and Nucleic Acid-Based Therapies and Embryology and Developmental Toxicity Testing

Outcome:

Very useful meeting. A lot of new science is presented and is also a great opportunity for networking, meeting with CROs, collaborators and colleagues. Learned a lot WRT safety evaluations of untraditional therapies (e.g stem cells and gene therapy). This is not trivial and regulatory interaction and advice is often needed.

Notes:

Date of activity start/end: March 13–17, 2017

Number of credits claimed: 15

Additional evidence:

Category: General Interest Academic Professional

Activity

Title of Activity:

Speaker at Biologics Symposium (Envigo).

Venue:

Lundbeck, Copenhagen, Denmark

Description of activity:

I enjoy teaching postgraduate students and it is also a great opportunity if you wish to develop your own scientific and teaching skills

At this symposium I talked about positive findings in carcinogenicity studies, their relevance and regulatory implications. Cases were presented and discussed with audience

Date of activity start/end: May 18, 2016

Number of credits claimed: 1

Additional evidence:

Category: General Interest Academic Professional

Activity

Title of Activity:

Minipig Research Forum (MRF).
EEMGS Annual Meeting. Copenhagen, Denmark

Venue:

Copenhagen, Denmark

Description of activity:

The Minipig Research Forum (MRF) is a non-profit organisation for everyone working with Minipigs. The MRF was launched in 2007 and has more than 450 members. Every year, a meeting for all members of the MRF is arranged and this meeting is a unique opportunity for Minipig users to meet and interact.

Topics discussed at the European Environmental Mutagenesis and Genomics Society (EEMGS) meeting were: Bridging genomics, human environmental health risk assessment and the 3Rs in animal science, Evaluating a complex genotoxicity data set for relevance to humans exposed through the diet.

Date of activity start/end: May 26-27 and August 14–18, 2016

Number of credits claimed: 11

Additional evidence:

Category: General Interest Academic Professional

Activity

Title of Activity:

22nd Annual Biotechnology-Derived Therapeutics: Perspectives on Nonclinical Development Symposium.

Venue:

Newport Beach, CA

Description of activity:

The Charles River Biotech Symposium is a stimulating educational forum where drug development professionals come together to discuss innovations and issues in the nonclinical development of biotherapeutics. Colleagues shared the latest data on monoclonal antibodies, growth factors, vaccines, stem cell therapies, immunomodulatory agents and other biological entities. Additional sessions addressed challenges that arise during nonclinical development, including safety concerns and the ever-changing regulatory landscape.

Date of activity start/end: September 19-21, 2016

Number of credits claimed: 12

Additional evidence:

Category: General Interest Academic Professional

Activity

Title of Activity:

Biopharmaceutical Training: Developing Monoclonal Antibodies (Covance)

Venue:

Copenhagen, Denmark

Description of activity:

This was a full day biopharmaceutical course designed specifically for my employer and focused very much on the clinical aspects of drug development. Topics were: Overall strategic considerations for Mab development, Mab structure and the relationship with to mechanism of action and safety, First time in human studies with Mabs, Transition from Phase I to Phase II and beyond: key clinical considerations for Mab development and Immunogenicity assessment for monoclonal antibodies.

This was of great relevance and value to our R&D since Mabs are now high on the company's agenda.

Date of activity start/end: October 27, 2016.

Number of credits claimed: 5

Additional evidence:

Category: General Interest Academic Professional

Activity

Title of Activity:

Reading of various journals, book and papers with focus on the non-human primate and minipigs in non-clinical development of biologics

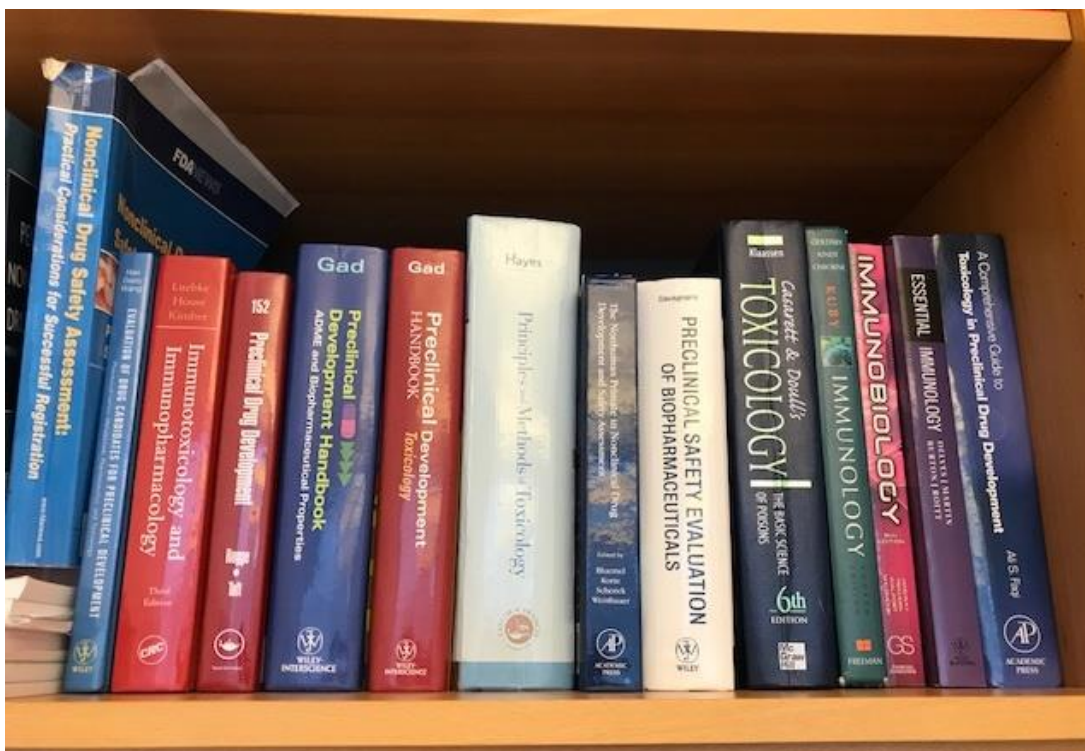
Reading of various journals, book and papers with focus on embryology, developmental and juvenile toxicity testing

Venue:

Copenhagen, Denmark

Description of activity:

My employer has historically only worked with small molecules but in 2014 decided to start developing biologics (monoclonal antibodies) for the treatment of inflammatory skin diseases. In order to become familiar with preclinical drug development and toxicity testing of Mabs I consulted and read (some) of these books:



Date of activity start/end: 2015

Number of credits claimed: 25

Additional evidence:

Category: General Interest Academic Professional