UNICA Network of Universities from the Capitals of Europe

in cooperation with

EPSA European Pharmaceutical Students' Association

UNICA STUDENT WEBINAR ON
"PHARMA AND BIOTECH CAREERS IN EUROPE (PART I)"

23 Nov 2020 10 am CET

Participation is free
Zoom link: https://us02web.zoom.us/j/81720732304
Further information: http://www.unica-network.eu/taxonomy/term/3611
and luciano.saso@uniroma1.it

FINAL PROGRAMME

WELCOME AND INTRODUCTION (15`)

Luciano Saso, UNICA President
Josef Kunrt, Vice President of Education, European Pharmaceutical Students' Association (EPSA)
Sibel Suzen, Professor of the Faculty of Pharmacy, Ankara University and Member of the UNICA Steering Committee
Josse R Thomas, Guest Lecturer, *KU Leuven* and Senior Consultant, PharmaCS

SESSION 1. LIFE AFTER ACADEMIA

What Student expect after a degree in Pharmacy or Biotechnologies? by *Josef Kunrt and Andreea Iordache*
Educational Affairs Coordinators, European Pharmaceutical Students' Association (EPSA) *(15')*

Launching your pharma/biotech career in Europe by *Chris van Schravendijk,* Emeritus professor at the Faculty of Medicine and Pharmacy of the Vrije Universiteit Brussel. *(*15')

Overview of opportunities for jobs and careers in the pharma, bio- and medtech sector in Europe by *Josse R Thomas*, Guest Lecturer, *KU Leuven* and Senior Consultant, PharmaCS

Discussion (15')

Comfort break (10')

SESSION 2: OPPORTUNITIES IN NON-CLINICAL DRUG DEVELOPMENT

Job opportunities in Drug Discovery by *Cristina Gardelli,* Research and Early Development │Respiratory & Immunology, AstraZeneca, Mölndal Sweden (15')

ADME, career opportunities in preclinical and clinical drug development by *Glyn Steventon,* Chemical Biological Radiological Division/ Toxicology, Trauma and Medicine Group, Defence Science and Technology Laboratory (*Dstl*) UK (15')

Career Opportunities in Nonclinical Development (toxicological studies) by ***Mark Martens***, Former vice-president of nonclinical development of Tibotec (J&J) and consultant in preclinical development and toxicology *(*15')

Discussion (15')

CLOSING: *Luciano Saso & Josse R Thomas (*5')

UNICA Network of Universities from the Capitals of Europe

in cooperation with

UNICA STUDENT WEBINAR on
PHARMA AND BIOTECH CAREERS IN EUROPE (PART II)

14 December 2020 10 am CET

Participation is free

Zoom link: https://us02web.zoom.us/j/81240828418
Further information: http://www.unica-network.eu/taxonomy/term/3611
and luciano.saso@uniroma1.it

PROGRAMME

WELCOME AND INTRODUCTION (15`)

Luciano Saso, UNICA President
Mihai Ioniţă EPSA President, European Pharmaceutical Students' Association (EPSA)
Sibel Suzen, Faculty of Pharmacy, Ankara University
Josse R Thomas, Guest Lecturer, *KU Leuven* and Senior Consultant, PharmaCS

PRESENTATIONS

Job opportunities in the Clinical Research Organizations world by ***Benedikt Van Nieuwenhove***, Managing Director ECCRT (15')

Job opportunities in Clinical Research Quality Management by ***Iris Gorter de Vries***, Director of Quality Assurance at SGS Life Sciences, Mechelen, Belgium *(*15')

Job opportunities in marketing and medical affairs by *Vicky van den Nieuwenhuyzen,* Marketing Director, Servier, Belgium (15')

Job opportunities in regulatory affairs by ***Ann Emmerechts***, Senior Director, EU Head of Regulatory Sciences, BeNeLux and Switzerland/Austria clusters, Bristol Myers Squibb (15')

Career opportunities in a Science Park by *Laura Aldrovandi*, Senior Project Manager Fondazione Democenter – Sipe, Tecnopolo Mario Veronesi and ***Simona Sbardelatti,*** Project Manager D7-Finance Srl, Tecnopolo Mario Veronesi, Italy

Discussion (30')

CLOSING: *Luciano Saso & Josse R Thomas (* 5')

Prof. Luciano Saso (Faculty of Pharmacy and Medicine, Sapienza University of Rome, Italy) received his PhD in Pharmaceutical Sciences from Sapienza University in 1992. He is author of more than 230 scientific articles published in peer reviewed international journals with impact factor (SASO-L in www.pubmed.com, total impact factor > 500, H-index Google Scholar 47, Scopus 38). He coordinated several research projects and has been referee for many national and international funding agencies and international scientific journals in the last 30 years. Prof. Saso has extensive experience in international relations and he is currently Vice-Rector for European University Networks at Sapienza University of Rome. In the last 15 years, he participated in several projects and has been speaker and chair at many international conferences organised by the UNICA network of the universities from the Capitals of Europe (http://www.unica-network.eu/) and other university associations. Prof. Saso has been Member of the Steering Committee of UNICA for two mandates (2011-2015) and he is currently President of UNICA (2015-2023).

Mihai Ioniță has recently graduated pharmacist from Bucharest, Romania. He is **President of European Pharmaceutical Students' Association** for the 2020/2021 mandate and also intern in AESGP (Association of the European Self-Care Industry), working from Brussels, Belgium.

Professor Sibel Suzen, Ankara University, Faculty of Pharmacy, UNICA steering Committee member. Sibel Süzen is professor at the Faculty of Pharmacy of Ankara University. Her research is focused on the synthesis and development of antioxidant-based anticancer compounds, their biological evaluation, melatonin-based compounds in drug research. She graduated from Ankara University Faculty of Pharmacy in 1985. After completing her Master's Degree in Pharmaceutical Chemistry at the same university in 1989, she received her doctorate in 1997 from the University of Swansea, UK, Department of Chemistry. She continued her research at Swansea University in various years. She has been a member of European Farmacopea expert in Group (Semi synthetic and synthetic compounds) since 2011. In the last 10 years, she has been working as Institutional Erasmus Coordinator, Internationalization and Foreign Relations Coordinator of Ankara University. She has been coordinating the opening of English taught programs as well as international projects, internship agreements and educational programs of the EU. She was vice-rector for International Relations and Projects at Ankara University since 2019-20. She carried out numerous projects supported by Tübitak and University resources. She is the author of more than 100 scientific articles and many chapters in various books both in Turkey and abroad. She worked as project manager and organized several scientific meetings. She has been a member of the Editorial Board of various scientific journals.

What do students expect after a degree in Pharmacy or Biotechnology?
European Pharmaceutical Students' Association (EPSA)

Many students are entering the studies full of enthusiasm and with a clear vision of their future career possibilities. Throughout the years, things get blurry and they discover that what seemed like an easy choice, in the beginning, is far more complicated than they expected. The main issue is that even though many possible career paths are available for the students, they don't feel prepared enough for any of them. This situation is the result of multiple reasons, ranging from outdated or lacking knowledge obtained during the studies to insufficient work experience opportunities. During this presentation, we will showcase the differences between students' career-related expectations and the reality of the job market, while providing you with some possible explanations for the discrepancies. In the end, we will present several initiatives developed by EPSA (European Pharmaceutical Students' Association) with the aim of helping students overcome those challenges, by complementing the knowledge offered by universities and preparing them for future careers as healthcare professionals.

Josef Kunrt has recently graduated a Faculty of Pharmacy, Charles University in Czechia and he is the current **EPSA Vice President of Education.** During his studies, he has been involved in local students association, where he was responsible for various educational activities, but also leading the association and communication with external parties. This gave him a big overview of the needs of pharmacy students and at the same time, he learnt about the different stakeholders and their views in the field of pharmacy. Josef was also a student representative in the faculty's academic senate, where he was focusing on the curriculum and its changes. He recently moved to Brussels where he is and Public affairs & advocacy intern in Medicines for Europe.

Andreea Iordache is a recently graduated Pharmacist from Romania and the current **EPSA Educational Affairs Coordinator.** She discovered early in her studies the passion for research and was involved in multiple projects. Over the years, she participated in numerous national and international events organized by students and professionals, where she had the chance to expand her pharmaceutical-related knowledge, but also to understand that a true healthcare professional should possess a wide range of Soft-Skills. In 2019 she became an EPSA Soft-Skills Trainer, motivated by the idea of guiding people towards discovering their full potential. During her studies, she had several internships in hospital pharmacy and the pharmaceutical industry, which gave her a bigger insight into what is required from a pharmacy graduate. She recently moved to Brussels and started her internship within EFPIA (European Federation of Pharmaceutical Industries and Associations).

Overview of opportunities for jobs and careers in the pharma, bio- and medtech sector in Europe

Josse R. Thomas, PharmaCS

There is a wealth of job and career opportunities for young academic graduates and specialists in life sciences and other disciplines in the pharmaceutical, biotech and medical technology (medtech) sector in Europe. This presentation is meant to give a brief overview of the many possibilities. In the first part, job opportunities along the drug/product life cycle will be discussed: in discovery research, in non-clinical and clinical development, and during commercialisation. While in research and development a sound scientific background is essential (and a PhD is a plus), successful marketing of innovative medical therapies (be it classic drugs, biologicals, ATMPs, or medtech products) require in addition good commercial and communication skills, so that a second diploma (e.g. Master of Marketing, MBA or Pharmaceutical Medicine) is rather a valuable asset. By contrast, the manufacturing of drugs/medical products is typically a world for industrial pharmacists and engineers. The second part will focus on support and management functions that are important during the entire drug/product life cycle, e.g. regulatory affairs, quality management, data management, biostatistics, scientific/medical writing, training, middle/senior/top management. Most of these professionals are life scientists, often with a postgraduate degree in the discipline concerned, and with previous experience in an operational function. The final part of the presentation will discuss career perspectives in this sector, e.g. progress from assistant or junior to senior professional, move up and become a senior or top manager, switch from a service provider or Clinical Research Organisation (CRO) to a proper pharma/biotech/medtech company, move from a company to a regulatory agency, switch back to academia, become an independent consultant, or start your own company.

Josse R Thomas graduated as a Pharmacist and holds a PhD degree in Medical Sciences (pharmacology) from the University of Leuven. He is also certified as Clinical Pharmacologist and has more than 30 years of experience in clinical drug development in the pharmaceutical industry. In addition, he holds various academic and consulting positions, including Guest Lecturer at KU Leuven (clinical drug development), member of the Research Ethics Committee of UZ/KU Leuven, member of the Clinical Trials Board of KCE, member of the working group at the FAMHP for the implementation of the EU Clinical Trials Regulation & Medical Devices Regulation in Belgium, and Senior Consultant at PharmaCS. He is also co-author of the book 'Global New Drug Development: An Introduction', published by Wiley-Blackwell, and a reference in its field.

Life after academia; launching your Pharma/Biotech career in Europe

Prof. Dr. Em. C.F.H. van Schravendijk – Brussels Belgium

Starting a European career in pharma/biotech requires a well-balanced set of *preparations*, *contacts* and *activities*. This set will vary depending on the particular focus of your interest, but it also shows some general characteristics and it is these that will be presented in this webinar. With respect to the *preparations*, we will look at the various options after pharma/biotech graduation and the important choices that have to be made, such as doing a PhD or not, the kind of additional training you take, finding the right balance between specialization and overall knowledge, key skills needed for any field of research and development. With respect to *contacts*, we will discuss the importance of projects with a link to industry, research environments with a clear link to applications in the heath sciences and umbrella organizations (such as FlandersBio) that provide access to a platform of pharma- and biotech organi-zations with job opportunities for graduates with or without a PhD degree. With respect to *activities*, we will discuss the post graduate options of strengthening your curriculum vitae with particular courses available in universities and/or industrial platforms, with for example a focus on language abilities, or on data and computer management, or on presentation techniques, or on patent law etc. These extra elements in your curriculum can make a major difference for employers for hiring you instead of another applicant that shares your area-specific background.

Chris van Schravendijk is Emeritus professor at the Faculty of Medicine and Pharmacy of the Vrije Universiteit Brussel. His research was focused on cellular biology, prediction and prevention of type-1 diabetes. As faculty professor he was responsible for the Introductory course on Scientific Thought and Evidence Based Medicine in the first Medical Bachelor year and for the Bachelor course on Formulation and Development of a Scientific Hypothesis in the third Bachelor year of Medicine and Biomedical Sciences. Between 2008 and 2016, he was the Director of the Doctoral School of Life Sciences and Medicine, with more than 200 PhD students. He has a long standing interest in international benchmarking and harmonization in the area of Higher Education (MEDINE, MEDINE-2, ORPHEUS) with focus on the place of the research component in the undergraduate medical curriculum as well as on career perspectives of academic graduates in the life sciences. As emeritus he is particularly interested in PhD workshops promoting better awareness of research integrity as well as job opportunities in the area of the Life Sciences.

Job opportunities in Drug Discovery

Cristina Gardelli, PhD – Associate Director – Medicinal Chemistry
Research and Early Development │Respiratory & Immunology, AstraZeneca Gothenburg, Sweden

Aim of this intervention will be to give a brief overview of the early phases of the Drug Discovery process and early development activities. The focus will be on more modern aspects of this complex activity. The drug discovery process starts with the identification and validation of a biological target, possibly based on a novel mechanism of action, to tackle an unmet medical need, which is not addressed by currently approved medicines. The biological target is then further investigated to identify the best chemical or biological modality that will be able to modulate it in a therapeutically useful and safe way. This modality will be explored in order to identify molecules with appropriate potency, selectivity and pharmacokinetic properties. The toxicology studies in at least two non human species are used to predict a safe dose to human and to allow the clinical stage development up to approval by regulatory agencies. During this journey, scientists with various different backgrounds work every day in a multidisciplinary environment, often across different countries and continents. In AstraZeneca, we have Early Talent programmes dedicated to college, undergraduate, master and PhD students. During this webinar, these opportunities will be discussed together with an overview on what a Great Place to Work means for us.

Currently I am Associate Director in the Medicinal Chemistry Department of Research and Early Development, Respiratory & Immunology at AstraZeneca in Gothenburg, Sweden where I lead a chemistry team and early stage respiratory projects in the lead generation and optimization phases. In AstraZeneca, I am actively involved in mentorship activities and I am a member of the “Great Place to Work” taskforce with the aim to build a culture where inclusion, diversity and sustainability are key values. I received my Doctoral Degree in Organic Chemistry from the University of Pisa in Italy, followed by postdoctoral research on total synthesis of natural products at the University of California, Berkeley. I joined AstraZeneca in 2010, after 14 years of research in the antiviral area at Merck Research Laboratories in Rome, where I was part of the team that discovered the first in class HIV Integrase Inhibitor, Isentress, approved for medical use in 2008.

ADME, career opportunities in preclinical and clinical drug development

Glyn B. Steventon

Pharmaceutical ADME Specialist, Dstl, UK

The main aim of drug development is to have a compound that has a therapeutic effect into the form of a medicine can be dosed to patients. A drug must reach the site of action, exert its pharmacological effects, and be eliminated in a reasonable timeframe – preferably to allow once-per-day dosing. Characterization of absorption, distribution, metabolism, and excretion (ADME) properties help to explore and explain how pharmacokinetic processes happen, so as to provide safety considerations of a new drug on which risk-based assessments can be made. Absorption, distribution, metabolism, and excretion are processes that together describe a drug's overall disposition via pharmacokinetics, or what the body does to a drug. ADME data can be collected at many stages in a drug's development pipeline. In discovery and lead optimization, drug developers may make chemical modifications to drug candidates to optimize ADME properties. As a drug moves forward through preclinical development and clinical phases, in vitro and in vivo studies provide critical information needed to meet regulatory expectations and equip drug developers to make informed decisions. There is no one degree pathway that leads to a career in ADME, degree level entry via biochemistry, biomedical sciences, biology, biotechnology, pharmacy and pharmaceutical sciences to name but a few are all good starting points for a successful career in ADME.

Glyn Steventon is a Pharmaceutical ADME (Absorption, Distribution, Metabolism and Excretion) Specialist at Dstl (Defence, Science and Technology Laboratory, UK). His career includes academia, industry (managing director of ADMET Solutions Ltd) and government positions and he has over 33 years' experience in the areas of clinical and pre-clinical drug metabolism, pharmacokinetics, pharmacogenomics and toxicology at the in vivo and in vitro level in both human and experimental animal species and over a hundred publications in the field. His areas of research when in academia were biomarkers of disease susceptibility in Parkinson's disease and ALS. He was part of the team that developed the MSc in Analytical Toxicology at King's College London and was programme director of the MScs in Applied Toxicology, Clinical Pharmacology and Pharmaceutical Medicine while at the University of Surrey. In industry he has provided preclinical and clinical ADMET support to both pharmaceutical and biotech companies in drug development.

Career Opportunities in Nonclinical Development

Mark Martens, PharmD, PhD, ERT

Nonclinical development, in contrast with discovery, is a heavily regulated activity and leads to documents that are required to introduce testing of the drug candidate in the clinic, to move it from one development phase to the next and finally obtain marketing authorisation as a drug. Nonclinical development as discussed in this presentation comprises the assessment of the safety and the bioavailability (does it reach the target in sufficiently high concentrations to exert a therapeutic effect without toxicity?) of the drug candidate as soon as it is released from discovery. The sciences involved in nonclinical development are safety pharmacology, toxicology and ADME (absorption, distribution, metabolism and excretion). Nonclinical efficacy is usually taken care of by the discovery department specialized in the pharmacology of the drug candidate and clinical development once the drug candidate is approved to be used in patients. Nonclinical development and pre-clinical development are terms which are used interchangeably but often pre-clinical development is referred to as the phase preceding the first administration of the drug candidate to healthy volunteers. Nonclinical development produces the data that are required to pass to the next phase of clinical development and addresses safety and pharmacokinetic issues that have been identified in the clinic. Nonclinical development also covers safety aspects that cannot be assessed in the clinic such as reproductive toxicity, embryo-foetal development toxicity and carcinogenicity. There exist various ways on how nonclinical development is organised in the pharmaceutical industry and the interface between discovery and development can vary. However, in all cases drug development is based on a team effort. Once the drug candidate is released from discovery an early development team is formed which will lead the drug candidate to approval for entry into late development. Once approval is obtained then a late development team is formed which will lead the drug candidate to market approval. Nonclinical drug development is a contributing party to both teams. The nonclinical team leader is in charge of the nonclinical team to which scientific disciplines contribute such as toxicology, safety pharmacology, pharmacokinetics and metabolism. Based on the various functions that are required in nonclinical drug development career opportunities and career paths are presented for scientists with university degrees such as biology, molecular biology, biotechnology, pharmacy, veterinary sciences, bio-engineering, chemistry, physics and statistics.

Mark Martens holds a degree in pharmacy of the University of Ghent, Belgium and obtained a PhD in pharmaceutical sciences from the same university in 1976. Afterwards, he joined Continental Pharma in Brussels, Belgium where he led the laboratory of mass spectrometry and drug metabolism for 3 years. Then, Mark joined the National Institute of Public Health (currently Sciensano) in Brussels where he started the department of toxicology and got involved in the hazard and risk assessment of industrial chemicals and pesticides in collaboration with international organizations (Commission of the EU, IPCS, IRPTC, IARC, ECETOC). After 10 years of government service, he joined the chemical and agrochemical industry (Monsanto) to take on the responsibility of chemical risk assessment (all products and manufacturing operations) of the Europe-Africa and Middle East regions first as a manager then as a director in the European corporate headquarters in Brussels and in the European Technical Centre in Louvain-la-Neuve, Belgium. He spent 2 years in the world headquarters in St Louis, United States where he was responsible for the toxicology of industrial chemicals worldwide. In 2004, Mark was invited to lead the toxicology operations for the development of antiviral drugs in the Johnson & Johnson virology franchise (Tibotec) where he was later appointed vice-president nonclinical development for all drugs. During that time he was involved in the development of drugs against HIV, RSV, hepatitis C and tuberculosis. Mark retired in 2010 from Johnson & Johnson and is since then active as an independent consultant in pre-clinical development and toxicology. Mark Martens is the author of numerous publications in the field of toxicology and pharmaceutical development and co-authored a book: “Global New Drug Development, An Introduction”, by Rosier JA, Martens MA, Thomas JR, ULLA Postgraduate Pharmacy series, Wiley Blackwell) where he provides an overview of the nonclinical development of drugs on a global level.

Job opportunities in the world of Contract Research Organisations (CROs)

Benedikt Van Nieuwenhove
Managing Director of the European Centre for Clinical Research Training

Within the entire drug development cycle, the research part that involves human beings, called clinical research, is by far the most resource intensive. Not only because of its duration and financial impact, but also because of the high human resource involvement. With over 50 different positions involved, clinical research is a very attractive area for building your career. Nowadays, more than half of the clinical research performed by pharma and biotech companies is outsourced to external organisations, contract research organisations. Hence why, starting your career in a CRO offers a wide range of possibilities. A background in life sciences is a requirement for a career in clinical research. But equally important are strong communication and management skills for being successful. In this webinar we will be discussing the possibilities the CRO industry offers when starting your career. An overview of the main positions will be provided using the clinical trial life cycle and finally, we will give hints & tips to become successful in the fascinating world of clinical studies.

Prof. Dr. Benedikt Van Nieuwenhove obtained his degree in Pharmaceutical Sciences from the University of Gent, Belgium in 1991. In 1997 he finished his Ph.D. in Pharmaceutical Sciences at the University of Gent in Belgium. After he obtained his degree in Pharmaceutical Sciences, he worked as a quality assurance manager at a laboratory for medical biochemistry & clinical analysis in Gent from 1991 to 1997. From 1997 to 2014, he worked for Harrison Clinical Research. He continued his career as a clinical operations manager and general manager of the Benelux operations. In 2000, he founded a training academy called the "European Centre for Clinical Research Training" (ECCRT) and in 2007 he became a member of the Board. From 2008 to 2011, he acted as the Vice President Global Operations of the Harrison Clinical Research group. In January 2011, he was elected Chief Executive Officer of Harrison Clinical Research. In that position, he was involved in the merger with Synteract to form SynteractHCR. He was instrumental in integrating the two organisations during 2013 and 2014. Since its creation in 2000, Benedikt has been the Managing Director of ECCRT. Having been in the field of Clinical Research for about three decades he has amassed a wealth of knowledge and skills within this field. Over the years he has supported the Pharma Industry as well as other players in the healthcare sector by providing them with the skill sets to deal with the challenges in their jobs and by helping make them more effective in their respective careers. Since 204 he has been Vice President and President of the Belgian Association of CROs (BeCRO). Since 2016, he has been lecturing “Management of Clinical Research” at the Faculty of Pharmaceutical Sciences, University Ghent and managing at the ECCRT.

Job opportunities in Clinical Research Quality Management

Iris Gorter de Vries, PhD
Director of Quality Assurance at SGS Life Sciences, Mechelen, Belgium

There are many jobs to be had in the area of Clinical Research Quality Management. We will discuss how quality in CR is related to subject safety and data credibility, the importance of compliance with regulatory requirements, the role of risk-based quality management and the challenge of data integrity. We will describe possible positions, such as Quality Manager, Auditor (with several focus fields), SOP (standard operating procedure) author, Quality Controller, Regulations expert and Compliance Manager. In all cases, a background in medical sciences, medicine, medical devices, pharmacy, pharmacology and related fields, with or without a PhD, is well suited. Understanding of clinical research is important and practical experience in that field is an advantage, but a lot can be learned 'on the job'. While quality management always requires you to be "quality minded", there is room in the field for people with different temperaments, from detailed oriented to more holistic, from technically focussed to people oriented. Thorough knowledge and understanding of your topic are needed to be able to help balance the requirements from quality and regulatory point of view with those of the operational teams who have to deal with short timelines and tight budgets.

Iris Gorter de Vries holds a master in biology from the State University of Leiden, the Netherlands, and a PhD from the Vrije Universiteit Brussel. She was instrumental at the start up of the Belgian Diabetes Registry at the VUB in 1989 and 1990. Iris then exchanged academia for the pharmaceutical industry by joining Pfizer as a clinical research associate for phase 2 and 3 trials, working in Benelux and Central and Eastern Europe. Setting up clinical research hubs in CEE, it became clear that support of these hubs with the development of a quality management system was needed. Iris set up and led a "Quality support" team in Brussels, working with headquarters on the one hand, and local CR office on the other. Later on, she joined the Pfizer global team for procedure development, training and quality management, supporting medical departments in country offices in Europe, Asia and the Americas. From 2009 to 2014, Iris worked as an independent clinical research consultant for Astellas Pharma, for a hospital Ethics Committee, and for a professional organization (ACRP) as developer of Good Clinical Practice training.
Since January 2015, she is Director Quality Assurance at SGS-Life Sciences, overseeing the quality management of the Clinical Research organization. In this role, she faces the exiting challenge of helping the business to comply with the Good Clinical and other Practices regulations and other applicable laws in the most effective and efficient way possible.

Job opportunities in marketing and medical affairs
Vicky van den Nieuwenhuyzen, Marketing Director, Servier, Belgium

After years of research and development a drug can finally be put on the market. The objective of the commercialisation phase is to generate return on investment and allow the development of new innovations. During this phase various departments play an important role: market access, regulatory affairs, medical affairs, pharmacovigilance, marketing, sales, ... In this meeting we will mainly focus on career opportunities in the medical affairs and marketing departments. These departments are central in the commercialisation phase of a drug. All scientific data collected over the years must now be translated into a clear strategy towards health care professionals (HCP) and patients. What are the needs of the various stakeholders in this market (doctors, pharmacists, payers, etc.) and in particular patients? How can we explain the added value of a drug to HCP and patients? A clear and strong communication plan (eg. Documents, congresses, press, Q&A, phase IV studies, ...) must be developed within a highly regulated environment. Therefore it's not only important to have a good scientific background. You also need to be familiar with the regulatory and deontological code, be analytical and have strong communication skills. Moreover, starting a career in medical affairs or marketing gives you a lot of insights and growth opportunities because you work closely together with other departments.

Vicky van den Nieuwenhuyzen obtained her degree in Pharmaceutical Sciences and Hospital Pharmacy from the University of Leuven, Belgium in 1998. When she started as Junior Product Manager at Servier, she discovered the fascinating world of the pharmaceutical industry. As a pharmacist she wanted to provide direct high quality patient care, as a product manager she wanted to be part of the pharmaceutical drug development which is evolving rapidly. Soon she became Senior Product Manager and in 2005 she was promoted to Cardiovascular Group Manager. She was responsible for the lifecycle management of some of the most prescribed antihypertensive drugs in Belgium. In 2016 she became Medical Director Cardiology. As such she was responsible for the marketing and medical affairs activities within cardiology at Servier. Since 2019, the marketing and medical affairs departments have been separated and Vicky is now Marketing Director, not only in cardiology but also in diabetes and chronic venous insufficiency. Thanks to her many years of experience in marketing and medical affairs, she has a specific expertise in patient-centric strategy and campaign management. She has been involved in many multi-channel projects, patient awareness campaigns, market access files, observational studies, ... Since 2017, she also shares her experiences with pharmacy students at the University of Leuven as a guest speaker.

Career Opportunities in Regulatory Sciences

Ann Emmerechts
Senior Director, EU Head of Regulatory Sciences, BeNeLux and Switzerland/Austria clusters,
Bristol Myers Squibb

The core business of the Global Regulatory Sciences (GRS) department is to drive the regulatory vision and provide high quality strategic leadership, and to manage regulatory processes in line with Business and R&D objectives. Goal is to ensure timely registration of new products and line extensions and as such *obtain marketing authorisations for medicinal products* with high unmet medical need, and manage the life cycle of the medicinal product. To do that it is important to be on top of the *pharmaceutical legislation and the development of procedural guidance*, to drive effective and consistent *communications with EMA (European Medicines Agency) and local Health Authorities*, and explore *innovative regulatory procedures and practices.* The regulatory function overall acts as a *key partner* to the Medical, Value, Access & Pricing, and Marketing departments, as well as to the Pharmacovigilance and GDP functions in the management of the life of the medicinal product. In addition to marketing authorisations, it is also the responsibility of GRS to submit *Clinical trial applications* to the competent authorities to obtain the necessary approvals to start clinical trials in a country, as well as contribute to the implementation of *Early Access Programs* in line with company policies and practices as well as local legislation, in order to provide access for patients to non-approved medicines. Within the function of Regulatory Sciences, there are different roles at *local (country), regional (EU) and global (HQ)* level. In addition, roles in GRS are found within regulatory *strategy,* regulatory *operations* and regulatory *policy*. For these functions a master or PhD in Life sciences is the desired education but different skills are needed. As science and technology are evolving rapidly, the regulatory professional has to be curious, flexible and agile and have continuously a learning mindset, be it in a large pharma company or a start-up, in a medical device company or at the side of the Health Agencies.

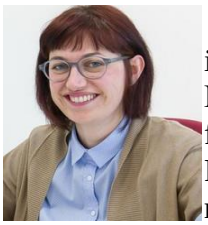
As Senior Director Global Regulatory Sciences Europe ***Ann Emmerechts*** has over 20 years of Regulatory experience in different therapeutic areas, companies, both at EU and national level. She is managing regulatory teams in UK/Ireland, Benelux and Switzerland/Austria, driving the regulatory vision and providing high quality, strategic leadership in executing regulatory activities and processes in line with Business and R&D objectives, she is a key partner and member of BMS Country Leadership Teams and GRS EU Leadership Team. Ann Emmerechts joined Bristol-Myers Squibb in 2002 as Associate Director in the Global Dossier Management group, heading the GRS Operations team in Europe. In 2009 she became Director Regulatory Sciences for the Benelux organization and had since then increasing responsibilities with extension to other countries, and in 2017 Head of GRS UK/Ireland, Benelux, Switzerland/Austria. Today she is Senior Director, Head of Regulatory Sciences, BeNeLux and Switzerland/Austria clusters, and in addition to the GRS EU Cluster Head role, she contributes to strengthening the regional EU regulatory voice in several initiatives, and supports the coordination of regulatory information across GRS-EU Strategy and national GRS teams. Before that Ann was Senior Manager EU Regulatory at Schering-Plough responsible for regulatory strategy and operational management of EU Marketing Authorizations. Ann has a degree as Pharmacist from the Free University of Brussels, as well as post-university degrees in Pharmaceutical Biotechnology (State University Ghent), EU Pharmaceutical legislation (University of Lille), and followed Leadership development programs at CEDEP-INSEAD (2016) and Columbia Business School NY (2017). Since 2018 Ann is a guest lecturer at the Catholic University Leuven, having a course in Regulatory Affairs & Market Access - Marketing authorizations.

Career opportunities in a Science Park

Laura Aldrovandi, Senior Project Manager Fondazione Democenter – Sipe, Tecnopolo Mario Veronesi and ***Simona Sbardelatti,*** Project Manager D7-Finance Srl, Tecnopolo Mario Veronesi, Italy

Mirandola biomedical district represents an international excellence composed by a group of companies specifically focused on the production of medical devices, both active (equipments) and non active (disposables). In fact, in 2016, the district was composed by almost 100 companies among multinationals and small/medium enterprises; occupying a total of approximately 4,500 employees and generating a turnover of almost 1 billion euro. Tecnopolo Mario Veronesi (TPM) was born in 2015 with the specific aim to improve the innovation helping companies during the whole life cycle of the medical devices: starting from the research and develpoment phase to the validation and commercialization of the product. TPM is a successful example of a Technological and Science parks, in fact it manages the knowledge and technology flows among universities, companies, R&D institutins and markets collaborating with all of them. Moreover, TPM helps the creation of new business through the start ups' incubation. Several are the opportunities in the Biomedical sectors, beyond the R&D, that can help the students with degree in biochemistry, biomedical sciences, biology, biotechnology, pharmacy and pharmaceutical sciences to grow up in this interesting field. Focus of the intervention will be the explanation of the most sought professional roles and what are the required profiles.

Laura Aldrovandi graduated in Medical and Pharmaceutical Biotechnology in 2010 at the University of Modena and Reggio Emilia with a PhD in "Work, Development and Innovation" from Marco Biagi University Foundation. Starting from 2011, she works at the Democenter-Sipe Foundation. She has always been involved in the presentation, management and reporting of R&D projects, both for the Democenter-Sipe Foundation and for local companies, mainly from the biomedical district. Since 2013, she contributed to the design and construction of the Tecnopolo "Mario Veronesi", where she is currently responsible for the R&D projects, both for companies and for the TPM itself.



Simona Sbardelatti Graduated in Medical and Pharmaceutical Biotechnology in 2011 at the University of Moedna and Reggio Emilia. She took a 2nd level Master in "Management of medical devices" at Luiss Business School. Starting from 2018, she is involved in the in the presentation, management and reporting of R&D projects, both for the Democenter-Sipe Foundation and for local companies, mainly from the biomedical district.