Dutch Pharmacological Society

Nederlands Vereniging voor Farmacologie (NVF)

Accreditation rules for European Certified Pharmacologists (EuCP) with the DPS (NVF)

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Content

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NEDERLANDSE VERENIGING VOOR FARMACOLOGIE

DUTCH PHARMACOLOGICAL SOCIETY

Accreditation rules for European Certified Pharmacologist (EuCP) with the DPS

1. Introduction

The Dutch Pharmacological Society (DPS) is the organization of professional (basic) pharmacologists in The Netherlands. The DPS organizes scientific activities for its members and aims to advance the pharmacological profession and its application in the biomedical field. The DPS is internationally associated with the Federation of European Pharmacological Societies (EPHAR) and has harmonized their program for training and certification as a pharmacologist to comply with the EPHAR accreditation rules for European Certified Pharmacologist (EuCP).

EPHAR has defined a number of qualifications to which scientists should comply to obtain their accreditation as a EuCP. Within the EPHAR Guidelines for Certification, the national societies such as the DPS for the Netherlands, are responsible for the primary certification procedure for the EuCP. For this a National Certification Board is the body to detail requirements for certification and a process for application and evaluation of the DPS program in line with the EPHAR Guidelines (https://www.ephar.org/eucp).

To that end, the DPS has installed a National Certification Board (NCB) for the EuCP to finetune the program and develop and check the process of certification as EuCP in the Netherlands. The accreditation program comprises elements of scientific knowledge and practical skills. The conditions for accreditation as a certified, professional pharmacologist including the procedure for application, examination and evaluation are described in this document.

2. Profile of a EuCP

A EuCP is an expert with appropriate scientific and theoretical knowledge and practical skills in pharmacological experimentation and evaluation regarding pharmacodynamics and pharmacokinetics of medicinal compounds. This implies that EuCP will be able to design/criticize experiments on pharmacokinetic, drug-target-interaction- and pharmacodynamic principles to allow proper evaluation of medicinal compounds. The area of expertise of a EuCP ranges from molecular receptor pharmacology in cell-lines, to pharmacokinetics and pharmacodynamics in laboratory animals and ultimately in humans. The EuCP is capable to apply state of the art technology such as “pharmacogenomics”, “functional genomics” and “proteomics” in combination with more classical experimental techniques in cell systems, isolated organs or in vivo models.

This allows the EuCP to participate in a multidisciplinary environment with other professional biomedical investigators in projects to assess, evaluate and document the mode of action of potential medicinal compounds, as well to play a subject matter expert role in the (pre)clinical

development of new drugs and those on the market. Examples of positions where the EuCP can be employed include laboratories for drug discovery and development, institutes for (academic) education, evaluation and documentation of drug action in (academic) hospitals, pharmaceutical companies, and government institutes.

3. Basis for professional training and accreditation as EuCP

The profession of pharmacologist is subject to continuous changes, both internally (as a discipline) and externally (the environment in which pharmacology plays a role). This is caused by the increased multidisciplinarity in drug research regarding discovery as well as development processes (process instead of discipline oriented). In addition, the use of a wide variety of technologies derived from other fields such as molecular biology and cellular biology (pharmacogenomics, functional genomics, proteomics) together with the possibilities to apply new imaging technologies and bioinformatics are at the basis of perpetual alterations.

The current training program for accreditation as EuCP has been approved in consultation between the national societies of pharmacology in EPHAR and gives recognition to the multidisciplinarity of the drug discovery and -development field. This implies that the program gives ways to train general pharmacologists as well as more specialized pharmacologists, with the prerequisite that all have a common understanding of and the ability to apply general principles in pharmacology which distinguishes his/her role and focus from other experts in the life sciences field. In addition, the program acknowledges the different specializations in the Dutch pharmacological institutes at the universities of Amsterdam, Groningen, Leiden, Maastricht, Nijmegen, Rotterdam and Utrecht.

The curriculum consists of knowledge and skills domains in modules that can be attended as courses and 'on-the-job training' on an individual basis. These courses can be received at the participating universities, graduate schools, and at e.g. BioSB (Bioinformatics and Systems Biology community in NL), the Dutch Techcentre for Life Sciences (DTL). On-the-job training is not limited to PhD training or post-doc positions at universities but can also be obtained in positions at pharmaceutical companies and governmental institutes.

4. Roadmap to qualify as a EuCP

DPS membership is mandatory for obtaining the EuCP qualification via the DPS.

4.1 Routes:

4.1.1 Juniors program:

Via a PhD-student program at one of the Dutch universities under supervision of a DPS-certified promotor and/or co-promotor, supplemented with a program in a post-doc phase in total for a minimum of five years.

Dependent on career path and opportunities of the candidate, attention should be given to a split in training for skills and competences in the PhD phase and in a post-doc position at a university, or on-the-job training elsewhere to fulfill the EuCP training requirement as referred to further in this document.

4.1.2 Seniors CV:

a) For those having a DPS Pharmacologist accreditation and working in an environment where they build on their pharmacologists' skills, can register as EuCP. This implies they should present an update of proof of their continued professional practice in a 'Portfolio'.

b) Those lacking the accreditation as DSP Pharmacologist, should present a complete Portfolio with documented proof of skills and competences obtained in pharmacology that satisfy the EuCP criteria as given below.

4.2 Procedures:

N.B.: All documents mentioned here can be found and downloaded from the DPS website: https://www.nvfarmacologie.nl; the latest versions are applicable.

4.2.1 Juniors program:

The candidate (PhD-student) is advised to use the document "EuCP Junior program application & portfolio" to **submit their training plan before starting their PhD**. This includes the following:

- Details for admission on education qualifications
- Plan for fulfilling the theoretical and practical training elements
- Details on the PhD program with sign-off of the tutor
- Portfolio for registration of activities
- This should be submitted to the secretary of the DPS National Certification Board (DPS-NCB, details at https://www.nvfarmacologie.nl

4.2.1.1 Criteria for admittance:

Criteria for admittance are:

Membership of the DPS (as an aspirant-member with reduced annual contribution);

a Master in a biomedical field (pharmacy, biopharmaceutical sciences, medical biology, medical biochemistry, biomedical sciences, medicine, veterinary medicine) at a Dutch university (or accepted as equivalent by Dutch universities as entrance level for a PhD-student program in a pharmacological topic).

Theoretical training items have to be selected as given in the excel sheet "NVF-EuCP.xlsx" at the DPS website, under 'Main' as well as 'Elective' Topics. Of note, there is limited choice in Main Topics as these represent the core domains of a pharmacologist, but plenty of differentiation is possible in the Elective Topics.

Practical training topics usually coincide with practical work being done for the PhD program, plus some broadening and extensions into other areas to get a more comprehensive knowledge in drug development as required for the EuCP accreditation.

The training comprises a span of 5 years, of which maximally 4 years can be part of a PhD project.

The NCB will evaluate the application for admission at the time the candidate will start its endeavor for EuCP training and will give their advice on the program, as follows. When the candidate applies their submission for certification, the NCB will evaluate the submitted proof of skills and competences against the certification criteria to grant for registration. Proof of skills and competences can be in the form of a Portfolio which includes verifiable PhD programs and supplementary studies, activities, exams, reports and assessments outside the PhD program, signed-off by supervisors, or by peer-reviewed publications.

4.2.1.2 Requirements:

The EuCP as well as the candidate in the EuCP training program should be an active member of the DPS.

Topics for theoretical training, practical training and skills are listed in the excel sheet NvF-EuCP.xlsx on the DPS (NVF) website (https://www.nvfarmacologie.nl). Criteria and courses are given in this excel sheet, but candidates may propose other means to fulfill mentioned criteria to the NCB for approval.

Theoretical training topics may be part of the Master degree at entrance (e.g. on "Principles of Basic and Clinical Pharmacology" as part of the curriculum of an MSc in Pharmacy at Dutch universities), may be obtained through courses, or may be studied as part of a practical study. In the latter case proof of competence of the end-terms of the topic as defined in a qualifying Masters course for the topic could be accepted in the form of a peer-reviewed scientific document (e.g. a publication, or a Regulatory document) such that the applicant's contribution can be verified by the NCB.

Theoretical courses should minimally be at a Master's level. Courses are graded in ECs (European Course equivalent).

A thesis project involving practical pharmacological studies at a Dutch university follows the final terms drawn up by these institutions and can qualify for a major part of the criteria for practical training and skills for the EuCP accreditation. However, attention should be given to documentation and verification against the listed terms for the topic and requires sign-off from the promotor or co-promotor of the thesis project. Further, a portfolio should be used to register activities and achievements. An example of this will be published at the NVF website.

Certification as EuCP requires that the applicant has contributed to at least 3 peer-reviewed publications, reports or assessments on pharmacological topics as proof of competence.

Additional competences:

- The candidate should have presented at least 5 review meetings on pharmacological topics (can be on own projects or topics from literature/congresses) within his/her work environment (e.g. department) and have attended at least 5 of such meetings presented by others.
- The candidate should have been involved in peer review for pharmacological projects, or scientific publications.
- The candidate will have attended at least 5 conferences/congresses with pharmacological topics of at least 1 day each.
- The candidate has given at least 3 scientific presentations at conferences of the DPS and at least 1 at a pharmacological conference outside NL, or was involved as Subject Matter Expert on a pharmacological topic in meetings with Competent Authorities for drug registration, or acting as an educator in a theoretical course on a pharmacological topic at Masters level at a Dutch university.

4.2.2 Seniors program:

a) Those with a diploma as DPS pharmacologist should present an update of proof of their continued professional practice in a 'Portfolio' (please take relevant parts of document "EuCP Junior program application & portfolio" as an example to make your portfolio)
b) Those without DSP diploma should present a complete Portfolio with documented proof of skills and competences obtained in pharmacology that satisfy the EuCP criteria and are invited to adapt the document " EuCP Junior program application & portfolio" accordingly. Most proofs of competence for seniors are likely to be presented in the form of publications.

Documentation should be submitted to the secretary of the DPS National Certification Board (DPS-NCB, details at https://www.nvfarmacologie.nl

5. National Certification Board/Accreditation Committee

The DPS appoints an Accreditation Committee (National Certification Board) from its senior members. This Committee consists of DPS members elected based on their knowledge of the field. The DPS-NCB is endowed to evaluate the curriculum of candidates in light of the requirements set by the accreditation rules defined in above sections “Roadmap…” and “Requirements”. Upon completion of the candidate’s application to the NCB with inclusion of its evidence, the NCB will take its decision for certifying unanimously. In case the NCB’s opinion is negative, the NCB will give the candidate specific recommendations on the deficiencies to prepare for re-submission. Upon approval, the DPS-NCB will recommend certification as EuCP to EPHAR and inclusion in the European Register of Certified Pharmacologists. The candidate can lodge an appeal against the decision of the NCB by motivating its points of dispute to the Board of the DPS. In such case the Board will meet with the NCB, discuss the application and decide on approval by simple majority vote.

6. Accreditation and renewal

The certification as EuCP is done by the EPHAR/EACPT EuCP Committee upon prior evaluation and recommendation by the National Certification Board. This certification is due after 5 years and re-registration is needed for continuation of registration. Re-registration requires an active membership of the DPS and continuation of professional use of the accreditation e.g. in a position in pharmacology (researcher, tutor, drug advisor, clinical specialist etc.) in academia, hospital, research and development, or government institute (e.g. Medicines Evaluation Board). Senior pharmacologists wishing to re-register should write an application for re-registration to the NCB and present their CV showing proof of continuation of an active career in pharmacology and continuing professional development (CPD) during their work. The latter should be provided as a list of CPD credible topics that were followed/executed and corresponding points based on https://eu-acme.org/cpd-cme-credit-system/number-of-credits-per-activity-type/, with a minimum of 250 CBU points/5y.

The administration of accreditations and renewal is organized by the DPS-NCB. The board of the DPS holds an annual meeting with the DPS-NCB to review/renew accreditations and will propose renewals as EuCP to the EPHAR/EACPT EuCP Committee.

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Appendix 1 – Requirements, Criteria and Institutions where Courses can be found

Topic #	Practical Training & Experience	Criteria	Erasmus UR	Radboud UN	RUG [1]	RUL [2]	UU	UM	VU	BioSB [3]
		General for ***training topics***: As course =3EC (1EC=28h) with exam, or with other verifyable proof of competence mentioned below								
1a 1b	Preclinical experiment design, statistical methods, data management and performance of in-vitro/ex-vivo studies Preclin experiment design, statistical methods, data management and performance of in-vivo studies	**At least one of topics 1 a-b as part of PhD thesis/qualifying studies as proof of competence.** The following elements should be mastered: preparatory work (litterature study, protocol writing, Animal Ethics Cie consent procedure & approval*, statistics and analysis and quality plan); experimental work (learning technology, study execution); Data cleaning, Calculations & Statistics; Reporting. For 3 projects a time spend estimation is 3000 h. *) In case of in vivo studies, the applicant needs to follow the required competency course for animal experimentation & animal welfare								
2	Preclin experiment design, statistical methods, data management	3EC course with exam, or contributor for mentioned topics in >4 publications of original work			•BCN Statistics Course 2019 (2EC) •Data management course	•Basic scientific computing for drug discovery •Data management 1-3				
3a	Biochemical and molecular techniques and diagnostics	at least two of topics 3a-f as 3EC course with exam, or as work experience with proof of competence								
3b	Clinical Trial design, management and GCP compliance									
3c	Pharmacogenetics and -genomics, epigenetics and other –omics									
3d	Determination of PK parameters and compound metabolism (drug concentrations in biological fluids and tissues and therapeutic monitoring)									
3e	pharmacoepidemiology, pharmaco-utilization and /or treatment optimization and individualization (through expertise in pharmacodynamics, pharmacokinetics, pharmacogenetics, therapeutic drug motitoring, etc				Basic Clinical Epidemiology course, Prof De Bock (3EC) (includes exam)					
3f	Pharmacoeconomics and/or Regulatory Affairs									
		Total minimally 6 EC on training for topics 2 and 3								

(cont'd on next page)

(For footnotes see next page)

4	Presentation of own pharmacology projects and attending discussion meetings of work presented by colleagues at the institute	Minimally 5 presentations of own work and attending 5 from others
5	Conduct of hands-on research for PhD thesis, company project, ... at institute 1	The combined program of theoretical and practical work should be spent in at least a time period of 5 years, with maximally 4 y in one institute
6	Conduct of hands-on research for PhD thesis, company project, ... at institute 2	
7	≥ 3 Publications on a pharmacological topic as first author	publications in peer-reviewed journals
8	Attendance of ≥1 multi-day congress with pharmacological topics per year during EuCP training period	proof e.g. by attendance certificate
9	≥ 3 scientific presentation concerning pharmacological topics at conferences, formal company meetings with regulatory bodies,...	proof e.g. by conference program, abstract book, ...

1) https://cursus1.webhosting.rug.nl/gsms/courses/research-techniques/?tx_seminars_pi1%5BshowUid%5D=968

2) https://www.universiteitleiden.nl/en/science/drug-research/phd

3) BioSB courses (Bioinformatics and Systems Biology community in NL): https://www.biosb.nl/education/course-portfolio/

Appendix 2 – Application & portfolio document DPS-EuCP Junior program 1.0 19-10-2020

Application for Registration in the Dutch Pharmacological Society- EuCP Juniors Program

Personal details of applicant

Name	
e-mail address	
telephone number	
Member of DPS since	
Relevant academic degree for EuCP program[1], Institute and date where obtained	

[1] See Document "Accreditation rules for European Certified Pharmacologist (EuCP) with the DPS"

Note to applicant:

The applicant should always use the latest information/forms given at the site of the Dutch Pharmacological Society: http://www.nvfarmacologie.nl.

There are three relevant documents to note:

1. "Accreditation rules for EuCP with the DPS",
2. Excel file for training topics and criteria for the EuCP program: "NvF-EuCP.xlsx"
3. This "Application & portfolio…." form.

This form is intended as a personal documentation file to submit to the National Certification Body (NCB) of the DPS (e-mail address given at the DPS site).

The first step is to select the type of application as explained in the 'Road map" text in Document "Accreditation rules for EuCP with the DPS".

This form is for junior investigators/PhD-students who want to enroll in a program that will qualify them as a EuCP as their first professional qualification as a pharmacologist.

The form can be filled out and sent to the NBC prior to/during a training (e.g.as PhD) to obtain comments from the NBC, or to apply for accreditation directly when ready.

Institute(s) where the applicant works/has worked for obtaining the EuCP accreditation

Institute 1	
Position	
Starting date **End date**	
Title of investigational program/job description	
Senior Pharmacologist to report to/tutor/Promotor/Department Head (include contact details)	
Other relevant information in relation to EuCP document 1[2]	

Institute 2	
Position	
Starting date **End date**	
Title of investigational program/job description	
Senior Pharmacologist to report to/tutor (include contact details)	
Other relevant information in relation to EuCP document 1[2]	

[2] "Accreditation rules for EuCP with the DPS"

Theoretical Training Topics[3]

Date	Main topics (7)	EC's	Institutional code of training module	Sign off[4]
	1. Principles of basic and clinical pharmacology (pharmacodynamics (PD), pharmacokinetics (PK))			
	2. Cellular, biochemical and molecular bases of drug action (therapeutic and toxic)			
	3. Drug(-drug) interactions (pharmacodynamic and as result of drug metabolism)			
	4. Experimental design, biostatistics and data management			
	5. Principles of organ pharmacology (organ bath and cell-systems pharmacology), or 'organ-on- a-chip' systems			
	6. R&D processes, including GLP			
	7. Ethical aspects of preclinical (including 3R principle), and clinical research			

Date	Elective topics (5)	EC's	Code	Sign off
	1.			
	2.			
	3.			
	4.			
	5.			

[3] In agreement with Document "NvF-EuCP.xlsx"
[4] Sign-off by tutor, department head, or else present (signed) documents/publications as proof

Practical Training & Experience[2]

1. Elective topics

Date	ElectiveTopics (4)	EC's	Code	Sign off[5]
	1. <at least one of 1a and 1b>			
	2. <mandatory topic>			
	3. < two from 3a-3f>			
	4. < two from 3a-3f>			

4. Presentation of own pharmacology projects and attending discussion meetings of work presented by colleagues at the institute

[*≥5 own pharmacology projects and attending ≥5 discussion meetings of work presented by colleagues at the institute*]

Date	Topic/title	presenter	Sign off[4]
	1.	<colleague/other scientist name>	
	2.	<colleague/other scientist name>	
	3.	<colleague/other scientist name>	
	4.	<colleague/other scientist name>	
	5.	<colleague/other scientist name>	
	6.	<yourself>	
	7.	<yourself>	
	8.	<yourself>	
	9.	<yourself>	
	10.	<yourself>	

[5] Sign-off by tutor, department head or refer to proof of competence in the form of a publication, report, etc

5. Conduct of hands-on research for PhD thesis, company project, ... at institute 1

Project description, including methodological details, purpose, etc (max 15 lines)

Signature of tutor/department head/supervisor/institute official,…for justification of the information given for topic 5:

Name and position: ……

Date : ……

6. Conduct of hands-on research for company project, post-doc,... at institute 2

Project description, including methodological details, purpose, etc (max 15 lines)

Signature of tutor/department head/supervisor/institute official,...for justification of the information given for topic 6:

Name and position: ……..

Date : ……

Application & portfolio document DPS-EuCP Junior program
1.0 19-10-2020

7. Publications on pharmacological topics in peer-reviewed journals as first author

1. <Vancouver style, please>
2. <Vancouver style, please>
3. <Vancouver style, please>

8. Congress attendance list

Date	Congress, place	credits
	1.	
	2.	
	3.	
	4.	
	5.	

9. Scientific presentations on pharmacological topics at conferences….

Date	Congress, place	Title of abstract
	1.	
	2.	
	3.	

Signature of applicant as statement for true information: ……

Name of applicant : ……

Date : ……

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