

MDRA-students

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MDRA-internship requirements

1) The **compulsory six-month internship (full-time; part-time accordingly longer)** must be completed in the field of “Drug Regulatory Affairs” in one of the following institutions:

- a) Pharmaceutical industry
- b) Contract Research Organisation (CRO)
- c) Regulatory authority
- d) Ministry
- e) Supervisory authority
- f) Consulting firm
- g) Institution of the Federal Armed Forces

2) During the internship, the knowledge acquired during the degree programme should be deepened and applied in practice. The internship can be split and can be completed at various training locations, at least 3 months should be completed in an institution acc. to 1a) or 1 b). The Examination Board may authorise exceptions to this rule upon justified request.

3) **Variation 1: Before beginning the internship**, an **application** must be submitted to the Examination Board (mdra-fahnenstich@uni-bonn.de, sample letters: A-regular job/B-internship, see appendix). Only periods after participation in at least six of twelve modules and completion of the associated study paper or project work will be approved as internships. In addition to the application, a **job confirmation from the employer** must be submitted (sample letter D, see appendix).

Within four weeks of the end of the internship, the intern must **submit a report** (on the work completed, including the time periods and weekly working hours. See appendix), **signed** by the intern and **countersigned** by the supervisor/line manager.

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4) Variation 2: In accordance with § 7 (6) of the examination regulations dated 18 July 2018, the Examination Board may also **approve a full-time job** (at least two years, part-time accordingly longer) as an internship, when completed within the six years prior to the beginning of the degree programme and within a relevant field of “Drug Regulatory Affairs”. The **application** and the **report** (on the work completed, including the time periods and weekly working hours. See appendix), **signed** by the intern and **counter-signed** by the supervisor/line manager must be submitted to the Examination Board (mdra-fahnenstich@uni-bonn.de, sample letter: C see appendix) at any time.

5) Please visit the career page on the website www.dgra.de for current job and internship offers.

6) Application and sample letters:

The application to be submitted must contain the following:

- 1) Name and address of the student
- 2) Declaration at which organisation(s) and during which period the internship is to be completed (If the period is not specified, the examination board will determine the period for formal reasons).
- 3) The working hours/week; regular working hours of a full-time position in the company.
- 4) Brief description of the function/activity to be approved as an internship.
- 5) Job confirmation from the employer for which period and in which area an internship/workplace is available (sample letter D, see appendix)

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APPENDIX

1) Sample letters

A) Application for approval of a **current professional activity**:

Dear Professor Jaehde,

I hereby ask you to consider my current full-time [*or part-time?*] employment at [*company's name*] in [*company's city name*] in [*department/division*] from [*xx.yy.ZZZZ*] to [*xx.yy.ZZZZ*] as an internship for the Master's programme 'Drug Regulatory Affairs'. In total, I have been working in regulatory affairs since [*xx.yy.ZZZZ*].

B) Application for approval of an **internship**:

Dear Professor Jaehde,

I hereby inform you that I would like to complete the internship [*full-time or part-time?*] for the Master's programme 'Drug Regulatory Affairs' at [*company's name*] in [*company's city name*] in [*department/division*] from [*xx.yy.ZZZZ*] to [*xx.yy.ZZZZ*].

C) Application for approval of a professional activity **prior to the Master's programme** acc. § 7 (6):

Dear Professor Jaehde,

I hereby apply for approval of my relevant professional activity at the [*company's name*] in [*company's city name*] in [*department/division*] from [*xx.yy.ZZZZ*] to [*xx.yy.ZZZZ*] (*at least 2 years full-time or accordingly longer if part-time*) as an internship in accordance with § 7 (6) of the examination regulations of 18 July 2018 for the Master's programme 'Drug Regulatory Affairs'. I enclose with this application a signed report countersigned by my supervisor/line manager on the work completed, including the time periods and weekly working hours.

D) **Job confirmation** from the employer:

Dear Professor Jaehde,

We hereby confirm that [*first name surname*], born [*xx.yy.ZZZZ*], is working in our company [*company's name*] in [*company's city name*] in [*department/division*] from [*xx.yy.ZZZZ*] to [*xx.yy.ZZZZ*].

2) Internship report

The following information should be included:

- Name of company/companies and department/s.
- Specification of the period and weekly working hours.
- Indicate your responsibilities and the start of the employment (if it is a professional activity already started before the internship period).
- Description in a formulated text and in the first person.
- Keyword-like listing of activities only possible if followed by formulated explanations.
- If possible, please describe the reference to the lectures (e.g. name modules and regulations).
- Describe your team, responsibilities and departments you work with.
- Describe software and tools normally used.
- Have you attend meetings or other training programmes?
- Own signature and signature of the line manager are required. Insert the following sentence: 'I (supervisor) hereby confirm that the information provided is correct.'
- If a supervisor's/line manager's signature cannot be obtained, a signed and qualified job reference is deemed to be a substitute.
- Page count: 5-15.

Within four weeks after completing the internship, the original or scanned report signed by you and countersigned by your supervisor must be submitted to the examination board (via e-mail to Dr. Jasmin Fahnenstich: mdra-fahnenstich@uni-bonn.de).