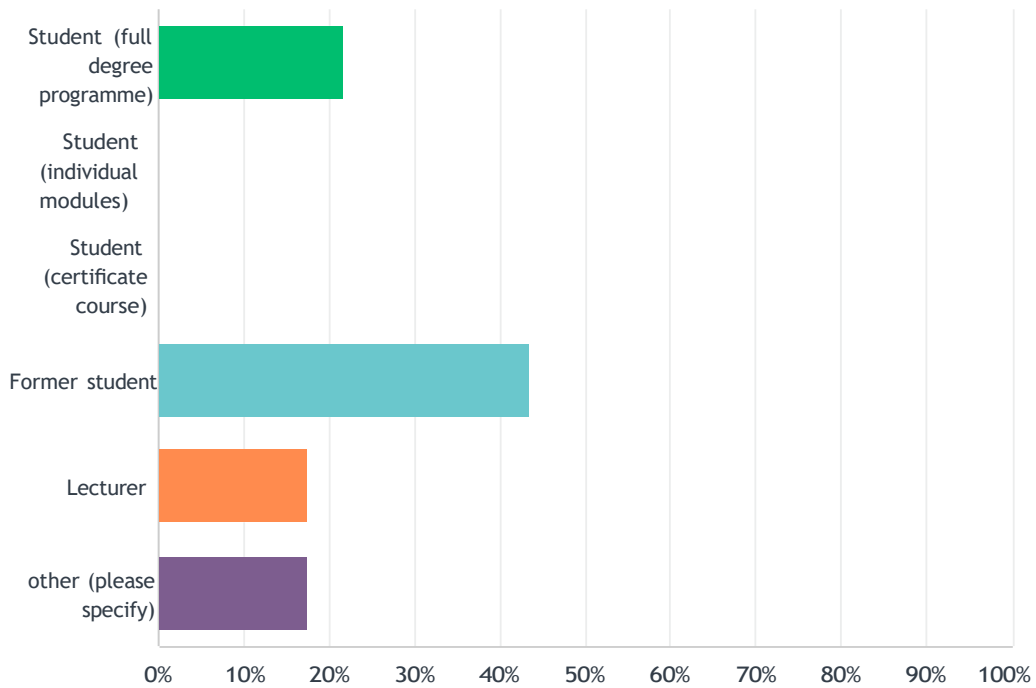


F1 How are you currently involved in the MDRA programme?

Answered 23 Skipped: 0

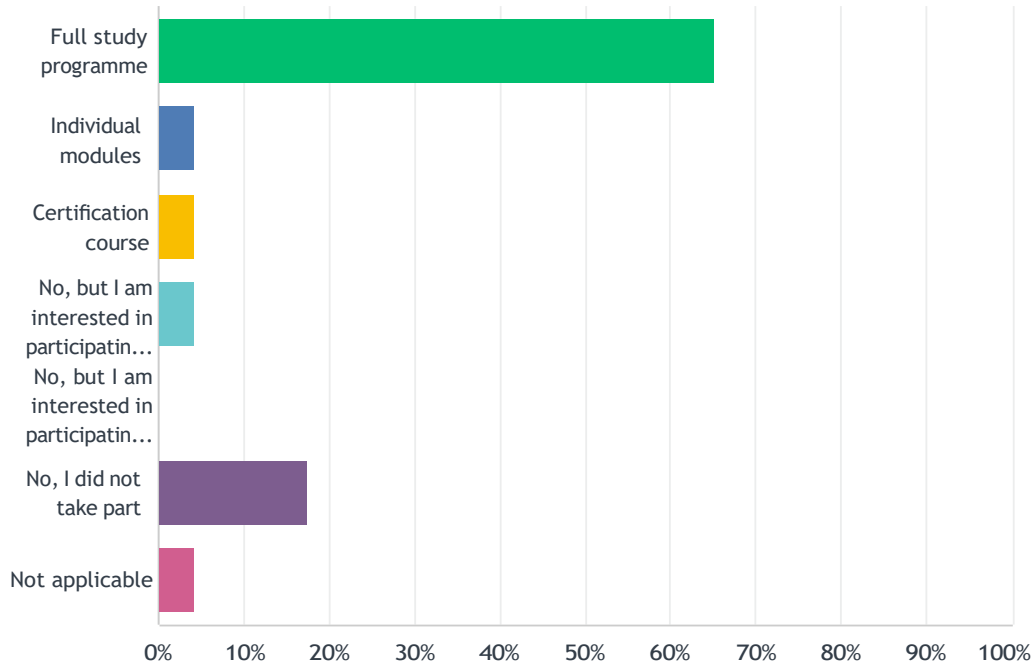


ANTWORTOPTIONEN	BEANTWORTUNGEN	
Student (full degree programme)	21.74%	5
Student (individual modules)	0.00%	0
Student (certificate course)	0.00%	0
Former student	43.48%	10
Lecturer	17.39%	4
other (please specify)	17.39%	4
TOTAL		23

Summary of responses 'Other': One person leads a CMC RA group and their employees participate in the programme. Another person is no longer involved and a third person shows interest in attending the course.

F2 Have you completed individual modules or the entire degree programme?

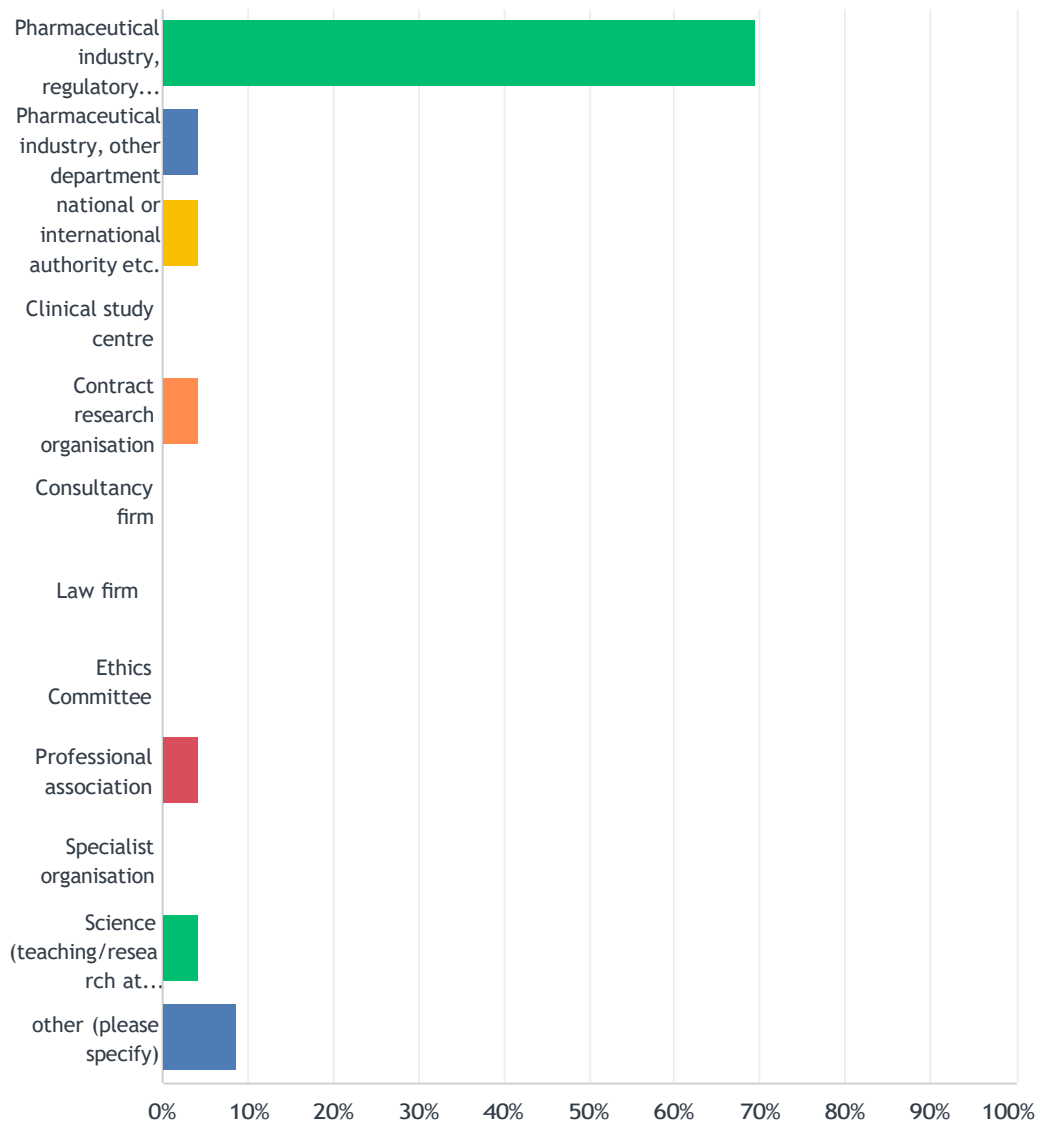
Answered: 23 Skipped: 0



ANTWORTOPTIONEN	BEANTWORTUNGEN	
Full study programme	65.22%	15
Individual modules	4.35%	1
Certification course	4.35%	1
No, but I am interested in participating in the full degree programme	4.35%	1
No, but I am interested in participating in individual modules	0.00%	0
No, I did not take part	17.39%	4
Not applicable	4.35%	1
TOTAL		23

F3 What area are you currently working in?

Answered 23 Skipped: 0



Survey on the MDRA degree programme

ANTWORTOPTIONEN	BEANTWORTUNGEN	
Pharmaceutical industry, regulatory affairs department	69.57%	16
Pharmaceutical industry, other department	4.35%	1
national or international authority etc.	4.35%	1
Clinical study centre	0.00%	0
Contract research organisation	4.35%	1
Consultancy firm	0.00%	0
Law firm	0.00%	0
Ethics Committee	0.00%	0
Professional association	4.35%	1
Specialist organisation	0.00%	0
Science (teaching/research at universities)	4.35%	1
other (please specify)	8.70%	2
TOTAL		23

F4 Regulatory Affairs (RA) is a very dynamic area. How do you see the development in the aforementioned areas and the future importance of an RA manager or RA expert?

Answered 20

Skipped: 3

Summary of responses:

1. **Increasing relevance of the RA Manager:** The role of the RA Manager remains important and is becoming even more relevant in the pharmaceutical industry, particularly with regard to strategic thinking, planning and knowledge of the latest trends. The facilitator role is particularly emphasised.
2. **Influence of AI and automation:** The tasks of the RA Manager are increasingly supported by artificial intelligence (AI) and automation, especially in routine activities such as dossier preparation and variation reports. Despite these developments, human expertise is still needed, especially in more complex, specialised areas of RA.
3. **Harmonisation and cooperation:** Harmonisation of regulations and greater cooperation between authorities and industry are emphasised. RA managers will need to develop project management and IT skills as the regulatory landscape becomes more complex.
4. **Continuing education and expertise:** Continuing education and updating knowledge are seen as essential to stay up to date in this dynamic field. There is an emerging trend towards specialisation and interdisciplinary collaboration.
5. **Outsourcing and consulting needs:** There are indications that legal work may be increasingly outsourced in the future, whether to consulting firms or through project-based contracts, particularly in light of the increasing complexity and cost of the new regulations.

F5 Why did you decide in favour of or against the degree/certificate course/individual module?

Answered 21

Skipped: 2

Summary of responses:

Chose the course because of career opportunities: Some participants had no previous experience in Regulatory Affairs (RA) and were looking for an opportunity to enter the field. The course helped them to gain a systematic overview and the necessary knowledge, which supported them in finding their first position in RA. Others opted for the course to deepen their knowledge of global regulatory landscapes and have a better chance of professional opportunities.

Recognition and value of the degree: Many emphasised that the degree (Master or Certificate) is considered well established and recognised and adds value to their professional profile. In particular, the DGRA Master's is seen as one of the few comprehensive training programmes in the field of RA.

Desire for comprehensive training: Some participants opted for the master's degree or certificate in order to receive comprehensive training in RA. They wanted to deepen their knowledge in various RA topics and achieve a formal qualification in the field.

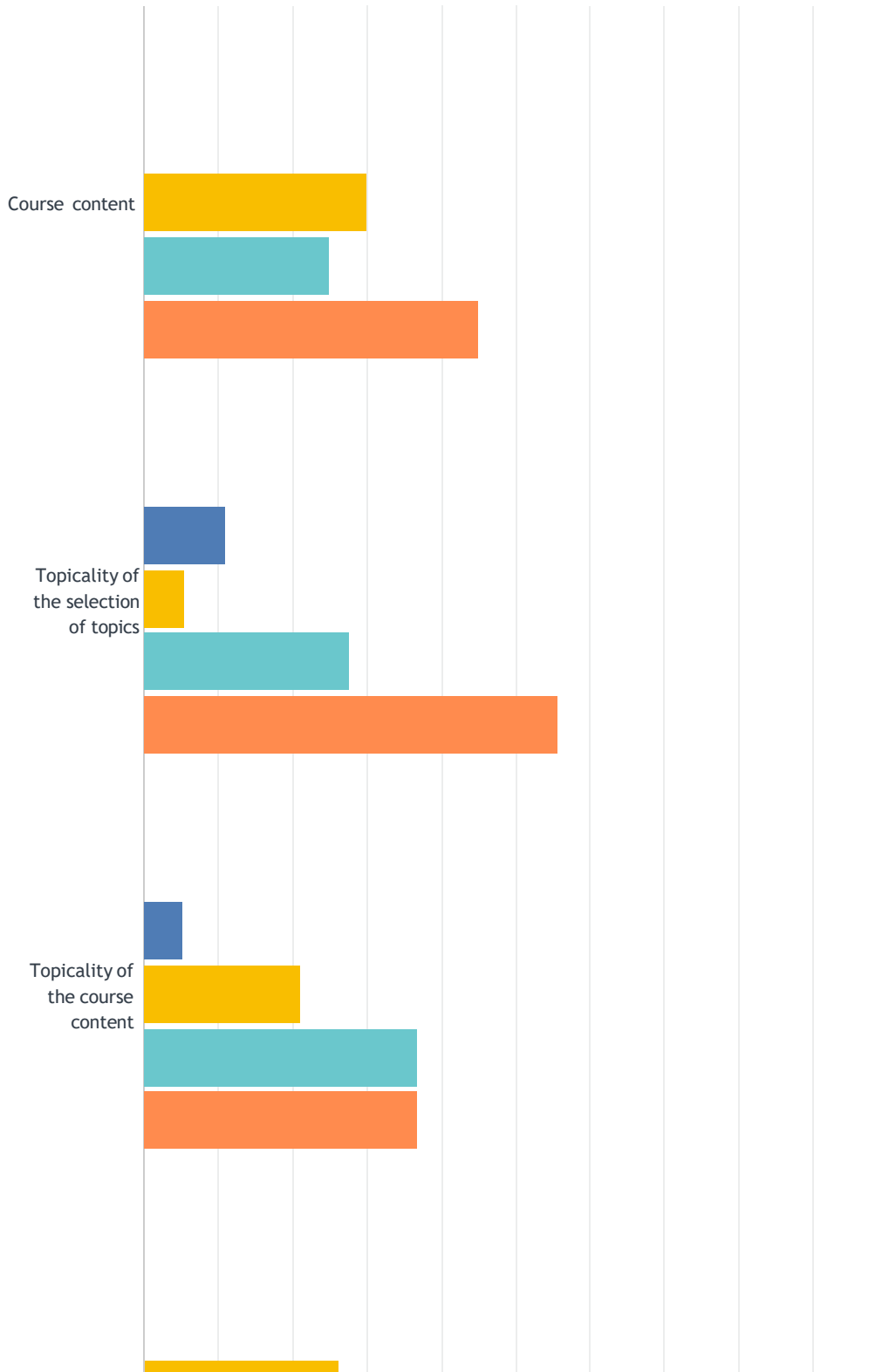
Time and professional challenges: However, it was also highlighted that it can be difficult to complete the programme in one year, especially when it comes to thesis supervision. Some participants decided to do the course to update their knowledge despite professional challenges.

Decided against the course: Some participants with extensive professional experience (around 20 years) decided against the programme as they already had in-depth knowledge.

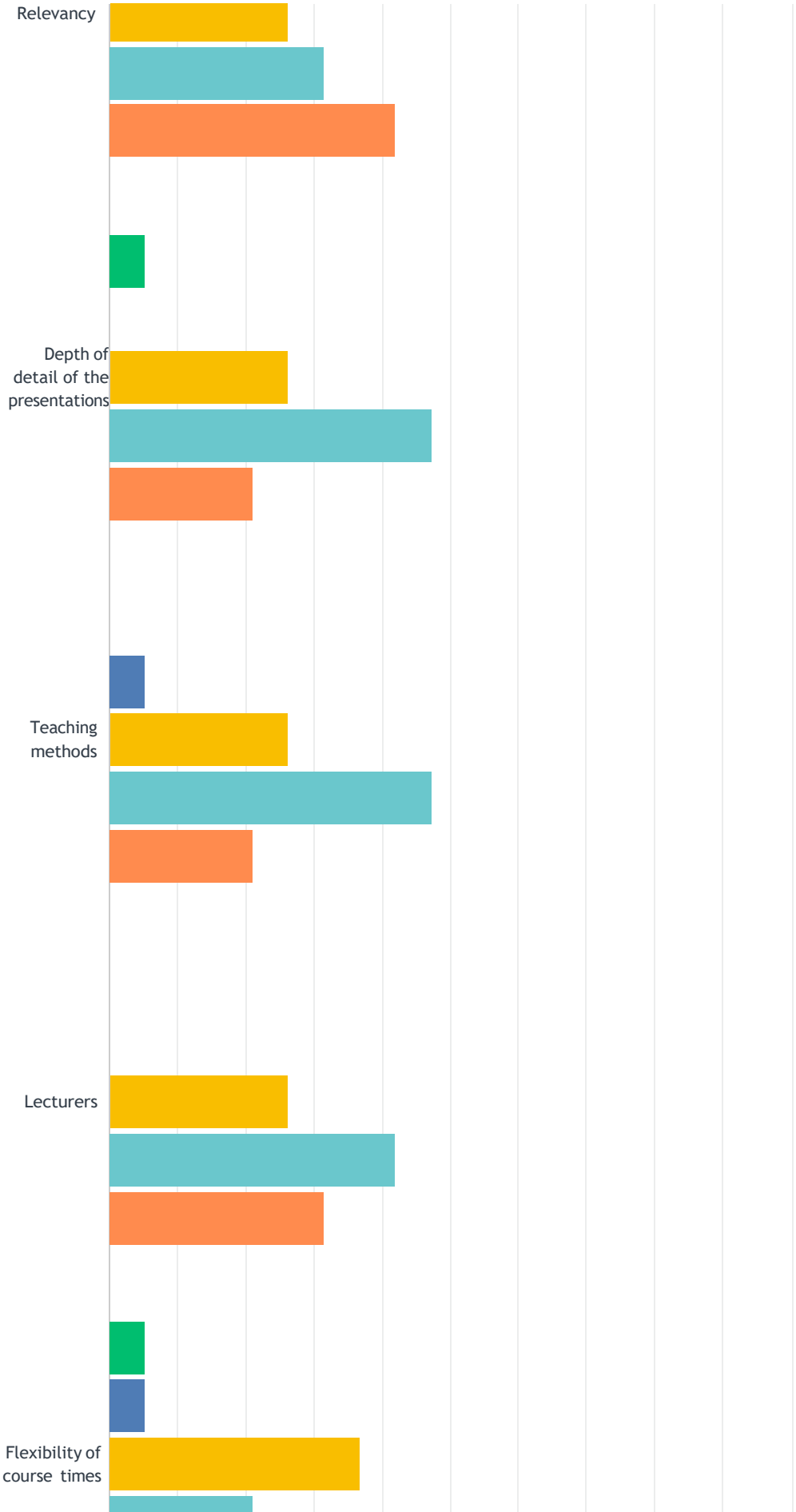
In addition, only a few modules were relevant for some people in specific areas (e.g. quality assurance).

F6 How satisfied are you with the following aspects of the current MDRA degree programme?(Please rate on a scale of 1 to 5, where 1 = very dissatisfied and 5 = very satisfied)

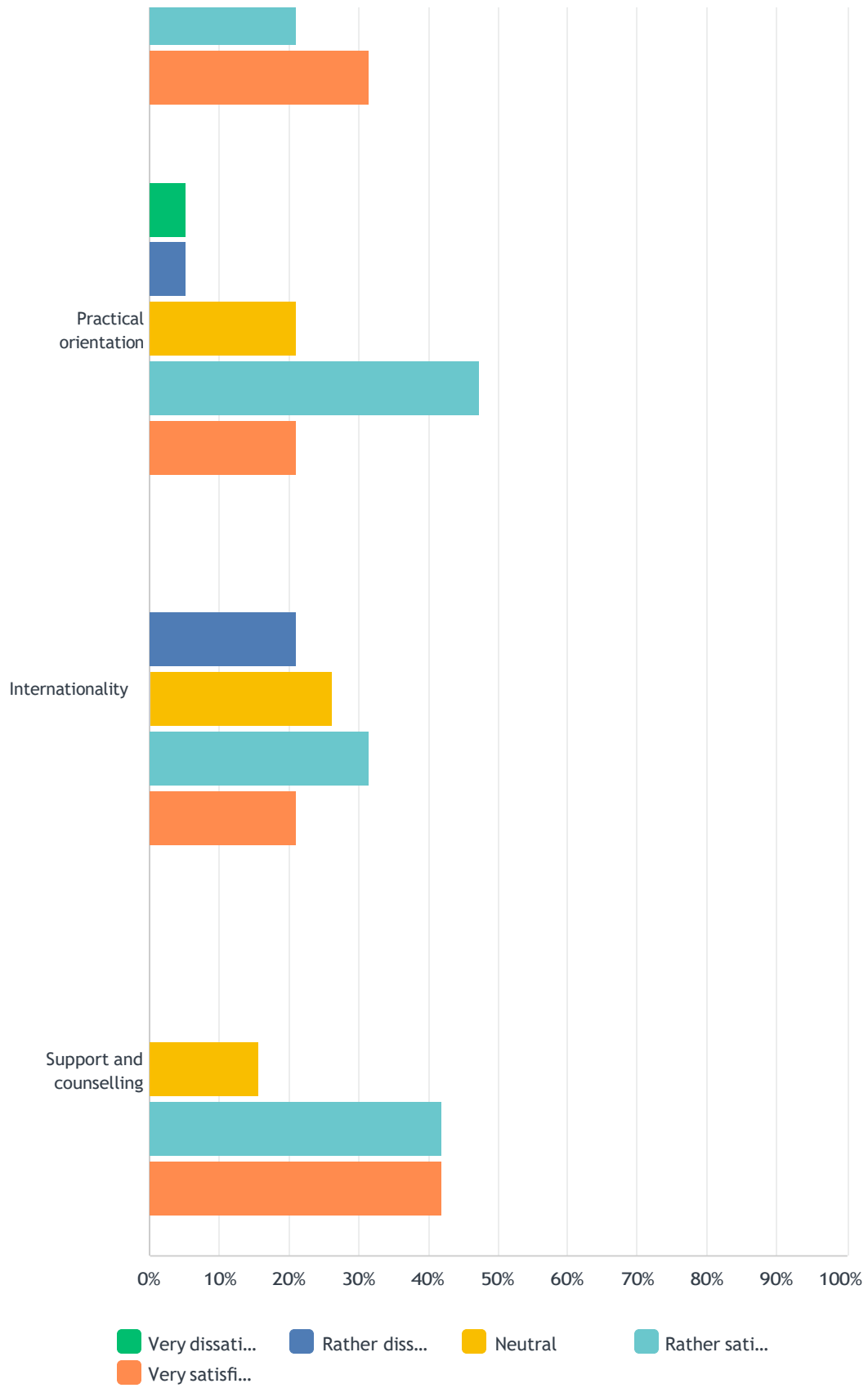
Answered 20 Skipped: 3



Survey on the MDRA degree programme



Survey on the MDRA degree programme



Survey on the MDRA degree programme

	0	1	2	3	4	5	TOTAL
Course content	0.00%	0.00%	30.00%	25.00%	45.00%		20
Topicality of the selection of topics	0.00%	11.11%	5.56%	27.78%	55.56%		18
Topicality of the course content	0.00%	5.26%	21.05%	36.84%	36.84%		19
Relevancy	0.00%	0.00%	26.32%	31.58%	42.11%		19
Depth of detail of the presentations	5.26%	0.00%	26.32%	47.37%	21.05%		19
Teaching methods	0.00%	5.26%	26.32%	47.37%	21.05%		19
Lecturers	0.00%	0.00%	26.32%	42.11%	31.58%		19
Flexibility of course times	5.26%	5.26%	36.84%	21.05%	31.58%		19
Practical orientation	5.26%	5.26%	21.05%	47.37%	21.05%		19
Internationality	0.00%	21.05%	26.32%	31.58%	21.05%		19
Support and counselling	0.00%	0.00%	15.79%	42.11%	42.11%		19

F7 What do you particularly like about the MDRA programme?

Answered 19

Skipped: 4

Summary of responses:

1. Diversity of lecturers: Participants appreciate the diversity of lecturers who come from different fields and backgrounds. This helps to better understand the perspective of regulatory authorities and promotes dialogue between students and lecturers.
2. Networking opportunities: Many participants emphasise the opportunity to network with other professionals from the regulatory industry. The exchange with colleagues from other companies and authorities (health authorities) is particularly appreciated.
3. Depth of content and variety of topics: The course is praised for its comprehensive topics and the expertise of the lecturers. The range of regulatory topics covered covers many aspects that are relevant to everyday working life.
4. Practical relevance and flexibility: Some participants mention the practical orientation of the programme, which helps them to apply what they have learned directly in their work. The flexibility and well thought-out curriculum are also positively emphasised.
5. Cooperation between industry and authorities: The cooperation between lecturers from industry and the authorities is seen as a valuable aspect of the programme. This enables students to gain both practical and theoretical perspectives.

F8 In your opinion, what are the biggest challenges or problems with the current range of degree programmes?

Answered 16 Skipped: 7

Summary of responses:

1. Time commitment and professional obligations: The programmes are very extensive and require a lot of time, which is difficult for working people. In particular, the combination of studying and a full-time job poses a major challenge.
2. Language barriers: Many potential participants who could benefit from the programmes are not proficient enough in German to follow the course. There is a need for programmes in English to appeal to an international target group.
3. Lack of practical relevance: Some programmes are too academic and theoretical and do not take sufficient account of the practical requirements of the industry. There is a need to close the gap between theoretical knowledge and real-world application.
4. Professional qualifications and requirements: In Germany, there are no standardised training requirements for regulatory affairs professionals. People are often hired without specific training or with related qualifications, which reduces the need for further training in this area. High requirements and motivation of applicants: The entry requirements, such as two years of professional experience in regulatory affairs, are difficult for some applicants to fulfil. In addition, some potential applicants lack motivation, especially if they already have alternatives in other professions.
5. Competition from other programmes: There are many competing programmes, some of which offer similar content. This makes it more difficult to differentiate yourself in the education market and attract the best students.
6. Health and organisational aspects: Sitting for long periods on consecutive days is perceived as unhealthy. There is also a desire for better networking and exchange opportunities among former students and lecturers.

F9 In your opinion, which of the following changes would make the MDRA programme more attractive? (multiple choice possible)

Answered 21 Skipped: 2

ANTWORTOPTIONEN	BEANTWORTUNGEN	
Adaptation of the course content	28.57%	6
Increase the practical component (e.g. through more internships)	23.81%	5
Increase interactive elements (e.g. more exercises, group work, short presentations)	33.33%	7
Better time flexibility (e.g. through additional evening programmes, increasing the proportion of online lectures or recorded lectures)	47.62%	10
Improving digital learning opportunities	47.62%	10
More intensive support and advice from the office team	0.00%	0
More intensive content-related support from the lecturers	14.29%	3
Internationalisation of the programme (English-language modules, selection of topics)	76.19%	16
Stronger networking with the industry	47.62%	10
other (please specify)	19.05%	4

Total respondents: 21

Summary of responses 'Other': It is suggested that the regulatory environment, such as the FDA (USA), China and India, should be given greater consideration.

It may be necessary to influence legal regulations in order to define more clearly who is authorised to work as a regulatory affairs professional.

One participant offered to be available as a guest speaker if required.

The application requirements should be improved.

F10 What topics or content would you like to see in the MDRA programme that are currently not covered or not sufficiently covered?

Answered 14 Skipped: 9

Summary of responses:

1. Expansion of international regulatory topics: More details on the submission process in Switzerland, international market with focus on China, Japan and expedited procedures. More international regulatory affairs, in particular more detailed insights.
2. Specific topic proposals: Advanced Therapy, development and evaluation of vaccines, ATMPs (Advanced Therapy Medicinal Products), and the use of technology to create dossiers.
3. Soft skills and leadership: More focus on leadership, communication and soft skills development.
4. Link to practice: More practical content and topics such as the transition to MDR/IVDR, GMP quality standards and challenges for companies.
5. Policy and sustainability: Impact of policy and supply shortages on public health, as well as environmental and sustainability issues.

F11 What skills should a graduate currently acquire in the MDRA degree programme in order to meet current and future requirements in the day-to-day work of RA?

Answered 14

Skipped: 9

Summary of responses:

1. Regulatory Knowledge:
 - a. In-depth understanding of the regulatory landscape and procedures, especially international requirements over local (German) regulations.
 - b. Basic understanding of the global regulatory environment, including knowledge of dossier content and essential modules (2, 3, 8-10, and all topics from Module 12).
2. Strategic and Project Management: Ability for strategic planning and effective project management to navigate complex regulatory processes.
3. Interpersonal and Communication Skills:
 - a. Strong intercultural skills and the ability to work in teams.
 - b. Effective communication and targeted problem-solving skills.
4. Digital Skills: Increasing emphasis on digital skills relevant to the evolving regulatory landscape.
5. Critical Thinking and Problem Solving: Skills in critical thinking and pragmatic problem solving are essential for addressing regulatory challenges.
6. Industry Awareness: Comprehensive understanding of industry stakeholders and interactions with authorities and third parties (e.g., Notified Bodies).
7. Job Experience: Practical experience is crucial, and internships are valuable for applying theoretical knowledge in real-world settings. Support for finding internships is important for fresh graduates.
8. Soft and Business Skills: A range of soft skills, including adaptability, networking, and an understanding of business dynamics, is essential alongside technical regulatory knowledge.
9. Overall, a balanced combination of technical expertise, soft skills, and practical experience is critical for success in the field of regulatory affairs.

F12 Do you have any specific suggestions for new teaching methods or didactic approaches to make the MDRA programme more attractive?

Answered 13

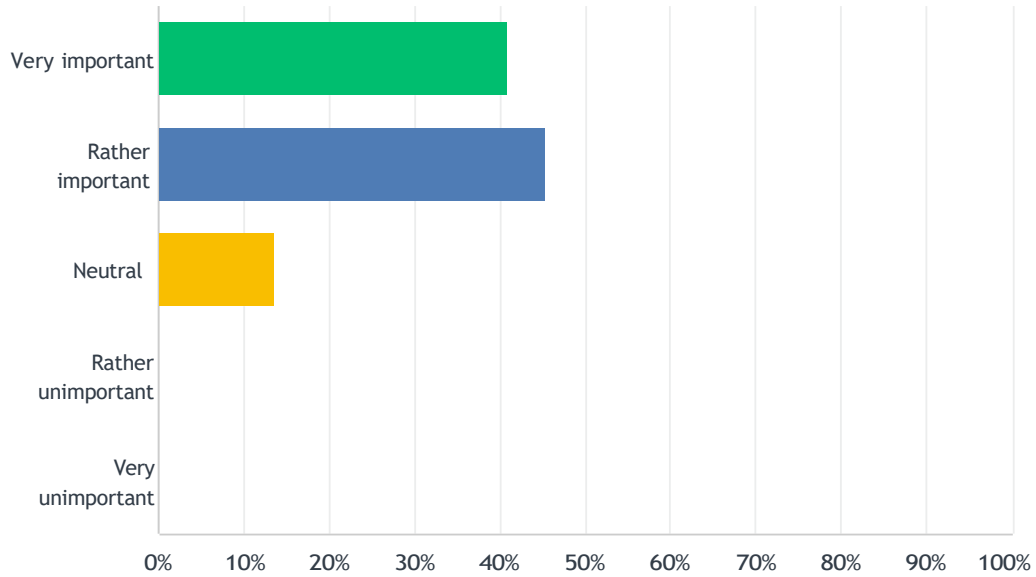
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Summary of responses:

1. Hybrid Learning: Offer a hybrid format for the course, allowing students to attend lessons both in-person and online.
2. Focus on Core Topics: Increase emphasis on Good Manufacturing Practice (GMP), Dossier Module 3, and inspection requirements.
3. Presentation Skills Development: Incorporate more presentation work to help students build digital skills and gain confidence speaking in front of an audience.
4. Project-Based Learning: Implement project-based learning to enhance practical understanding and engagement.
5. Consultation with Stakeholders: Seek input from specialized organizations and young professionals for insights on teaching methods.
6. Interactive and Practical Exercises: Introduce more exercises in modules 8, 9, and 10 to deepen understanding, potentially extending these modules over three weekends.
7. English Language Orientation: Develop an English-oriented program and consider advertising to attract a wider audience.
8. Interactive Methods: Use interactive teaching methods to engage students actively in their learning.
9. Lecture Recordings and Online Learning Platforms: Record lectures and provide access through an online learning platform for flexible study options.
10. Increase Case Studies: Incorporate more case studies to facilitate real-world application of regulatory concepts.
11. International Appeal: For a more international appeal, consider making the program online and bilingual (separate German and English programs) to attract a broader audience.

F13 How important is a university degree (MDRA) to you compared to a degree/certificate from a private education provider?

Answered 22 Skipped: 1



ANTWORTOPTIONEN	BEANTWORTUNGEN	
Very important	40.91%	9
Rather important	45.45%	10
Neutral	13.64%	3
Rather unimportant	0.00%	0
Very unimportant	0.00%	0
TOTAL		22

F14 Do you think that you currently need a (university) RA degree to start your career in the RA sector or is it possible without additional qualifications ('training on the job')?

Answered 19

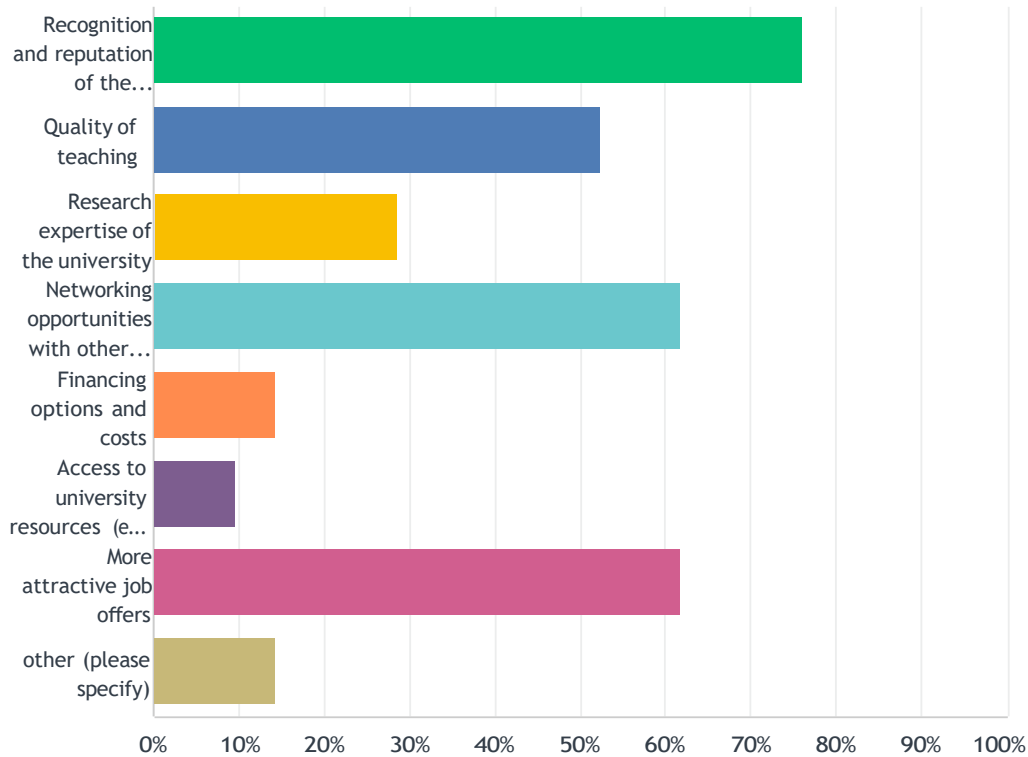
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Summary of responses:

1. **Possibility Without a Degree:** It is possible to start a career in regulatory affairs without a university degree or additional qualifications, often through "training on the job."
2. **Value of MDRA Degree:** While it's possible to enter the field without an RA degree, having an MDRA title is highly valued by employers and can provide a competitive advantage. Many respondents noted that having a university RA degree enhances career prospects and opportunities, particularly in companies that prioritize formal qualifications.
3. **Experience and Practical Training:** Practical experience and on-the-job training are seen as crucial components of a career in regulatory affairs. Some mentioned that while a degree is not essential, it is beneficial for building foundational knowledge and skills.
4. **Language Proficiency:** Knowledge of the German language at a high level (C1-C2) is often necessary to enter the German job market in regulatory affairs, regardless of other qualifications.
5. **Current Job Market:** The current environment, characterized by a shortage of workforce in regulatory affairs, may allow for entry without a formal degree, but the lack of educational qualifications can make the transition more difficult.
6. **Personal Experiences:** Several respondents shared personal views, indicating that entering the regulatory affairs field without experience can be challenging, emphasizing the importance of practical knowledge.

F15 What reasons are decisive for you in favour of a university degree over a private offer or not having a RA degree at all? (multiple choice possible)

Answered 21 Skipped: 2



ANTWORTOPTIONEN	BEANTWORTUNGEN	
Recognition and reputation of the university degree	76.19%	16
Quality of teaching	52.38%	11
Research expertise of the university	28.57%	6
Networking opportunities with other students and lecturers	61.90%	13
Financing options and costs	14.29%	3
Access to university resources (e.g. libraries)	9.52%	2
More attractive job offers	61.90%	13
other (please specify)	14.29%	3
Total respondents: 21		

F16 If you have completed the MDRA degree programme:

Answered 14 Skipped: 9

ANTWORTOPTIONEN	BEANTWORTUNGEN	
Have you gained any professional advantages as a result of your degree (e.g. career advancement)? (Yes/No)	92.86%	13
Were you able to use the content you learnt and the skills you acquired in your day-to-day work? (Yes/No)	100.00%	14

F17 What should be changed in the degree programme in order to be able to better apply the skills you have acquired in your career?

Answered 8

Skipped: 15

Summary of responses:

A stronger practical orientation of the study programme could be helpful in order to better apply the skills learned in a career. This could be done by incorporating practical examples and case studies.

One consideration would be to start the programme with an internship, especially for students with no previous work experience. Support in finding an internship could also be valuable. The possibility of completing multiple internships, for example two internships of four months each or a combination of experience in a regulatory agency and an industry internship, could enhance practical training.

In addition, a stronger link to industry could be established to provide insights into the day-to-day work of regulatory affairs professionals in different areas.

A shift towards a more business-orientated approach, rather than focusing solely on scientific content, could also be beneficial.

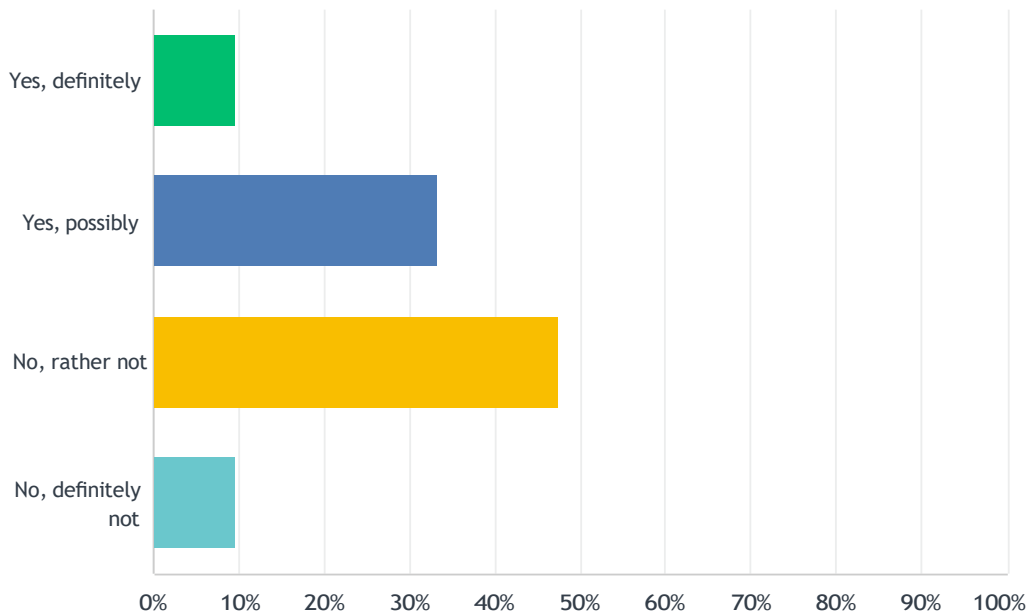
It would also be helpful to cover certain topics in more detail in the study programme to ensure a more comprehensive understanding.

The possibility of publishing student projects or theses in peer-reviewed journals could also increase academic quality and visibility.

Overall, the implementation of these proposals could help to better prepare graduates for their professional challenges in the field of regulatory affairs.

F18 Would a private education programme be of interest to you if it offered the same content as the university MDRA programme?

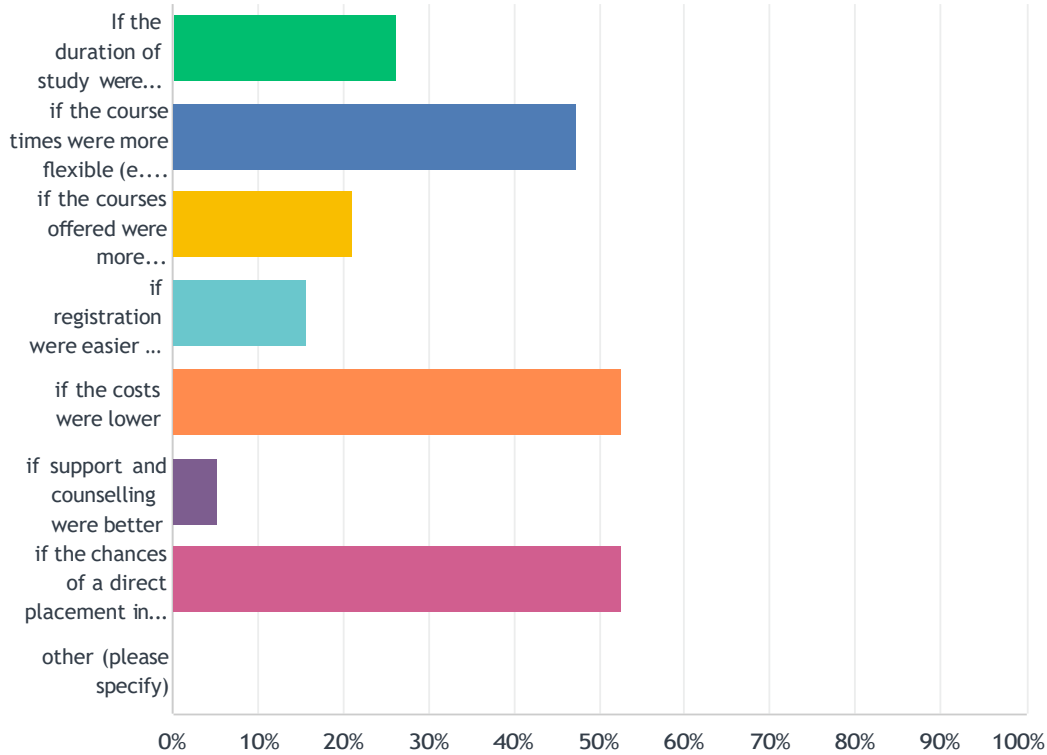
Answered 21 Skipped: 2



ANTWORTOPTIONEN	BEANTWORTUNGEN	
Yes, definitely	9.52%	2
Yes, possibly	33.33%	7
No, rather not	47.62%	10
No, definitely not	9.52%	2
TOTAL		21

F19 Under what circumstances would you prefer a private education programme to a university degree programme? (multiple choice possible)

Answered: 19 Skipped: 4



ANTWORTOPTIONEN	BEANTWORTUNGEN	
If the duration of study were shorter	26.32%	5
if the course times were more flexible (e.g. evening or online course, recorded course content)	47.37%	9
if the courses offered were more practice-orientated	21.05%	4
if registration were easier (no enrolment and admission requirements necessary)	15.79%	3
if the costs were lower	52.63%	10
if support and counselling were better	5.26%	1
if the chances of a direct placement in the industry were higher	52.63%	10
other (please specify)	0.00%	0

Total respondents: 19

F20 Do you have any further comments or requests on the subject of university versus private education programmes?

Answered 10 Skipped: 13

Summary of responses:

1. DGRA as a benchmark: Some employees of a survey participant recently attended the DGRA course, which is considered the gold standard in Germany and offers an excellent cost-benefit ratio.
2. Challenges in accessing the Master:
 - a. There are challenges in motivating Global RA team members to participate in the Master's: Many team members are not sufficiently fluent in German.
 - b. The time commitment is critical and can be difficult for employees who manage complex projects.
 - c. Some people find it difficult to attend the course in person in Bonn. The possibility of online participation could facilitate attendance.
3. Linking training and research: It would be helpful to link training with research activities and emphasise relationships with industry and regulators.
4. Certification of private programmes: It should be clear that private training is certified.
5. Adapt modules: Some modules, such as Module 11, may need to be reduced to allow more time for more important topics (e.g. Modules 2, 3, 8, 9, 10, 12).
6. Career pathways in RA: More awareness of career paths in regulatory affairs would be desirable.