



## Program: A4B Training School 3: Legal requirements, industrial applications and entrepreneurship

### A4B Training School 3 (09.11.20-13.11.20)-Day 1

Time	Workshop	Kind
<b>Host: Agilent</b>		09.11.2020
13:30-14:30	From Customer Input to Product Features: Marketing at Agilent	Seminar
14:30-14.45	Break	Break
14:45-15:45	A One Agilent Quality Management System	Seminar
15:45-16:00	Break	Break
16:00-17:00	Research & Development at Agilent, small r, big D	Seminar
17:00-17:10	Wrap up and Final QA	Seminar

### A4B Training School 3 (09.11.20-13.11.20)-Day 2

Time	Workshop	Kind
<b>Host: Hexal AG</b>		10.11.2020
9:00-10.20	Technical Bioassays and their role in the analytical CMC development program of a biological therapeutic molecule”	Seminar
10:30-11:30	Group Project: Elaborate a Bioassay case study	Breakout Session in predefined groups
11:30-12:00	ESR Presentations: Bioassay case study	ESR presentation
12:00-13:00	Break	Break
13:00-14:20	Patents for Biologics and Biosimilars	Seminar
14:30-16:00	Group Project: Elaborate a Patent case study	Breakout Session in predefined groups
16:10-16:40	ESR Presentations: Patent case study	ESR presentation
16:40-17:00	Wrap up and Final QA	Seminar



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### A4B Training School 3 (09.11.20-13.11.20)-Day 2

Time	Workshop	Kind
Host-Ludger Ltd		11.11.2020
9:00-9:10	Introduction/ Schedule presentation	Seminar
9:10-9:35	ICH Q2 R1 regulations	Seminar
9:35-10:00	Example of a validation using FSH	Seminar
10:00-10:30	Break	Break
10:30-10:40	Designing a validation for DMB	Seminar
10:40-11:30	Group Project: Design your own validation for FSH	Breakout Session in predefined groups
11:30-12:00	ESR Presentations: Design your own validation for FSH	ESR presentation
12:00-12:30	Presentation on the actual validation of DMB sialic acid	Seminar
12:30-12:40	Wrap up and Final QA	Seminar