

Bewertungsraster Bachelor Thesis																								
Name Studierende*r (inkl. Studienmodell)	Sabrina	Leuenberger																						
Art der Arbeit	Bachelor Thesis																							
Titel der Arbeit	BDD - A Practicable Approach for Computerised System Validation?																							
Vertraulichkeitsstufe	öffentlich / public																							
Studiengang, Modell & Standort	BSc Wirtschaftsinformatik	Teilzeit	Olten																					
Name Dozierende*r	Stephan	Jüngling																						
Auftraggeberschaft	wega Informatik AG																							
Vertreter/in der Auftraggeberschaft	Mathias	Fuchs																						
Ort, Datum	Basel	30.07.2020																						
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 60%;"></th> <th style="width: 20%; text-align: center;">Gewichtung</th> <th style="width: 20%; text-align: right;">Erreichte Punktzahl</th> </tr> </thead> <tbody> <tr> <td style="text-align: right;">Schriftlicher Teil</td> <td style="text-align: center;">90%</td> <td style="text-align: right;">237.50</td> </tr> <tr> <td style="text-align: right;">Mündlicher Teil</td> <td style="text-align: center;">10%</td> <td style="text-align: right;">93.50</td> </tr> <tr> <td style="text-align: right;">Erreichte Punktzahl Total</td> <td></td> <td style="text-align: right;">264.00</td> </tr> <tr> <td style="text-align: right;">- Abzug</td> <td></td> <td style="text-align: right;">- 0.00</td> </tr> <tr> <td style="text-align: right;">+ Modifikation</td> <td></td> <td style="text-align: right;">+ 0.00</td> </tr> <tr> <td style="text-align: right;">Gesamt Punktzahl</td> <td></td> <td style="text-align: right;">264.00</td> </tr> </tbody> </table>					Gewichtung	Erreichte Punktzahl	Schriftlicher Teil	90%	237.50	Mündlicher Teil	10%	93.50	Erreichte Punktzahl Total		264.00	- Abzug		- 0.00	+ Modifikation		+ 0.00	Gesamt Punktzahl		264.00
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Gesamtnote, nicht gerundet	6.0																							
Gesamtnote, gerundet auf 0.5 Note	6.0																							
Kommentar(e) schriftlicher Teil																								
I. Dokumentation & formale Vorgaben (Gewichtung: 14%)																								
Remarks Documentation Very good structured and systemaitc documentation. Chapter contents always focussed on particular topics. Good combination of text and visuals (e.g. BPMN models to compare specification and verification processes). Some of the theoretical aspects and explanations (e.g. BDD, Gherkin) could show less redundancy (e.g. explanations of Gherkin with the help of examples from literature could be replaced by definition of syntax tree and own examples).	100% der möglichen Punktzahl	Subtotal	33.25																					
II. Literaturrecherche & Theorie (Gewichtung: 16%)																								
Broad Literature review that covers the different important aspects of technical aspects of software specification, testing and validation, regulatory compliance issues and frameworks combined with good practices of agile software development (shared understanding of requirements by the "the tree amigos" in BDD).	100% der möglichen Punktzahl	Subtotal	38.00																					
III. Vorgehen & Analyse (Gewichtung: 16%)																								
In-depth analysis of the processes given by the standards and frameworks (e.g. GAMP5, BDD) showing the potential of BDD for the specification and automated testing and validation of the operational qualification of the developed applications, which is tranparently developed and documented. The requirements are very high due to the highly regulated market and plenty of compliance regulations. Very professional project management and good communication with all the involved stakeholders.	100% der möglichen Punktzahl	Subtotal	38.00																					
IV. Interpretation & Auseinandersetzung (Gewichtung: 16%)																								
Very demanding context of many regulatory requirements from the pharmaceutical industry. In-depth analysis of the testing and validation processes (e.g. GAPM5, BDD and the combination of both). Implementation of a working prototype based on a complex technology stack, using state-of-the-art testing and automation tools. Proper architecture, proper toolset, validation of the prototype with the help of an internal audit, correction of the initial defects, transparent and appropriate documentation of the results.	100% der möglichen Punktzahl	Subtotal	38.00																					
V. Zielerreichung & kritische Auseinandersetzung (Gewichtung: 18%)																								
The thesis states a set of relevant research questions at the beginning, which are thorowly addressed by in depth analysis of the process with respect to GAMP5 and BDD. Based on these insights, a prototype was implemented with the help of state-of-the-art testing and validation tools. The prototype is applied to a specific business application scenario and validated by an audit of a testing expert. First critical aspect (e.g. some issues with the documentation) revealed by the audit could already be addressed and the prototype meets the GxP quality standards, meets all requirements to implement an automated OQ process that is GAMP5 compliant.	100% der möglichen Punktzahl	Subtotal	42.75																					
VI. Lösungsentwicklung & Empfehlungen (nur für Projektarbeit und Bachelor Thesis) (Gewichtung: 20%)																								
An overall testing and validation process is developed based on an in-depth analysis with respect to GAMP5 and best practices drawn from BDD. The validity of such an automated test-approach is elaborated with several examples. With the help of a prototype, the feasibility of the approach could be demonstrated and the results are validated by an expert audit procedure. The proposed toolset (e.g. Gherkin, Scenariio, Selenium) and lifecycle management of the BDD artefacts (e.g. feature files, glue code, source code management and build tools) the associated OQ documentation is most appropriate.	100% der möglichen Punktzahl	Subtotal	47.50																					
Total schriftlicher Teil (von max. 237.5)			237.50																					
Formatierung & Erscheinungsbild	geringe Abweichung von HSW Leitfaden	5 Punkte Abzug																						
Geringe / Bedeuteude Abweichung	bedeutend: Format irreführend und inkonsistent	10 Punkte Abzug																						
Plagiat	klein: unsaubere Zitierweise festgestellt	bis zu 10 Punkte Abzug																						
	schwerwiegendes Plagiat erkannt	Note 1.0																						
FX Bewertung	heilbare Mängel im Teil I.	erreichte Note 3.5; maximale Note 4.0																						
Verspätet eingereicht	bis 24 Stunden verspätet	maximale Note 4.0																						
Ausserordentlicher Punktzuschlag	[Kommentar]																							

Bewertungsraster Bachelor Thesis

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Kommentar(e) mündlicher Teil			
I. Auftrittskompetenz & Medieneinsatz (Gewichtung 30%)			
At the beginning a little nervous, but overall very professional style of presentation. Questions asked could all be answered and put into the context, while pointing to further facts, which were not mentioned.		90% der möglichen Punktzahl	Subtotal 27.00
II. Inhalt (Gewichtung 70%)			
There are much more details in the written thesis, and many interesting aspects of the automatic testing. Some aspects could have been further visualized with the help of some demos of the prototype! With this respect, the presentation could only show very little of the many detailed evaluations and stayed a little on the surface. However, these aspects were illustrated very clearly (e.g. V-Model, example of features, BPMN diagram of the validation process).		95% der möglichen Punktzahl	Subtotal 66.50
		Total mündlicher Teil (von max. 100)	93.50
Gesamtwürdigung der Arbeit			
<p>The thesis aimed at demonstrating the validity to apply BDD in a highly regulated pharmaceutical sector, where the validation of computerised systems is most essential when new systems need to be tested before put into production. The manual validation of operational and performance qualifications (OQs, PQ) are costly and the analysis of the automation potential is highly relevant. The thesis did state appropriate research questions, which were resolved and answered systematically. The thesis provides an in-depth analysis of the testing and validation process with respect to current standard compliance frameworks with respect to the current best practices and state-of-the art tools from behaviour driven development, which seemed to be a perfect match.</p> <p>Based on the theoretical insights, a prototype for test-automation and validate of the OQs according to GAMP5 and GxP was built. This prototype was validated with the help of a wega internal audit of a testing expert.</p> <p>All research questions could be fully answered and the prototype is very valueable for the client. The current state of work exceeds the clients expectations and is seen as very valuable milestone for further investigations towards an operational automated validation process.</p>			
Die Dozentin / der Dozent bestätigt, dass die Arbeit bezüglich Einhaltung akademischer Standards überprüft wurde.			
Ort, Datum		Unterschrift Auftraggeberschaft	
Basel, 3.8.2020		Mit Auftraggeber besprochen	
Ort, Datum		Unterschrift Dozierende/r	
Basel, 18.8.2020			