RegCheck 2020

Expediting Your Drug Development
Using a Secure, Cloud-Based Platform

Introducing RegCheck™

- A secure, proprietary, cloud-based platform for driving drug development
- Audit trailed for all entries and changes
- Contains regulatory citations Health Authorities use to assess Sponsor's documentation
- All types of applications: IND, NDA, BLA, ANDA

RegCheck™ – Proven Process

- Developed by a team of regulatory and technical professionals at Hurley Consulting Associates as a quality tool to assure compliance with the regulatory requirements
- Used to bring more than 40 products to the market, over the past 30 years

Regulations to check…

109 Checklists covering Modules 3, 4 and 5

Contains over 4,500 questions

Linked to over 12,000 regulatory requirements

Key Benefits

- Immediate access to specific regulatory requirements
- Identifies and prioritizes potential issues that could prolong or derail FDA review and approval
- Helps to avoid costly late-stage rework and potential delays in bringing a product to market
- Helps users evaluate deficiencies for products considered for registration or acquisition
- Helps maximize the value of products that are to be divested
- Modular design – ***Use What You Need***

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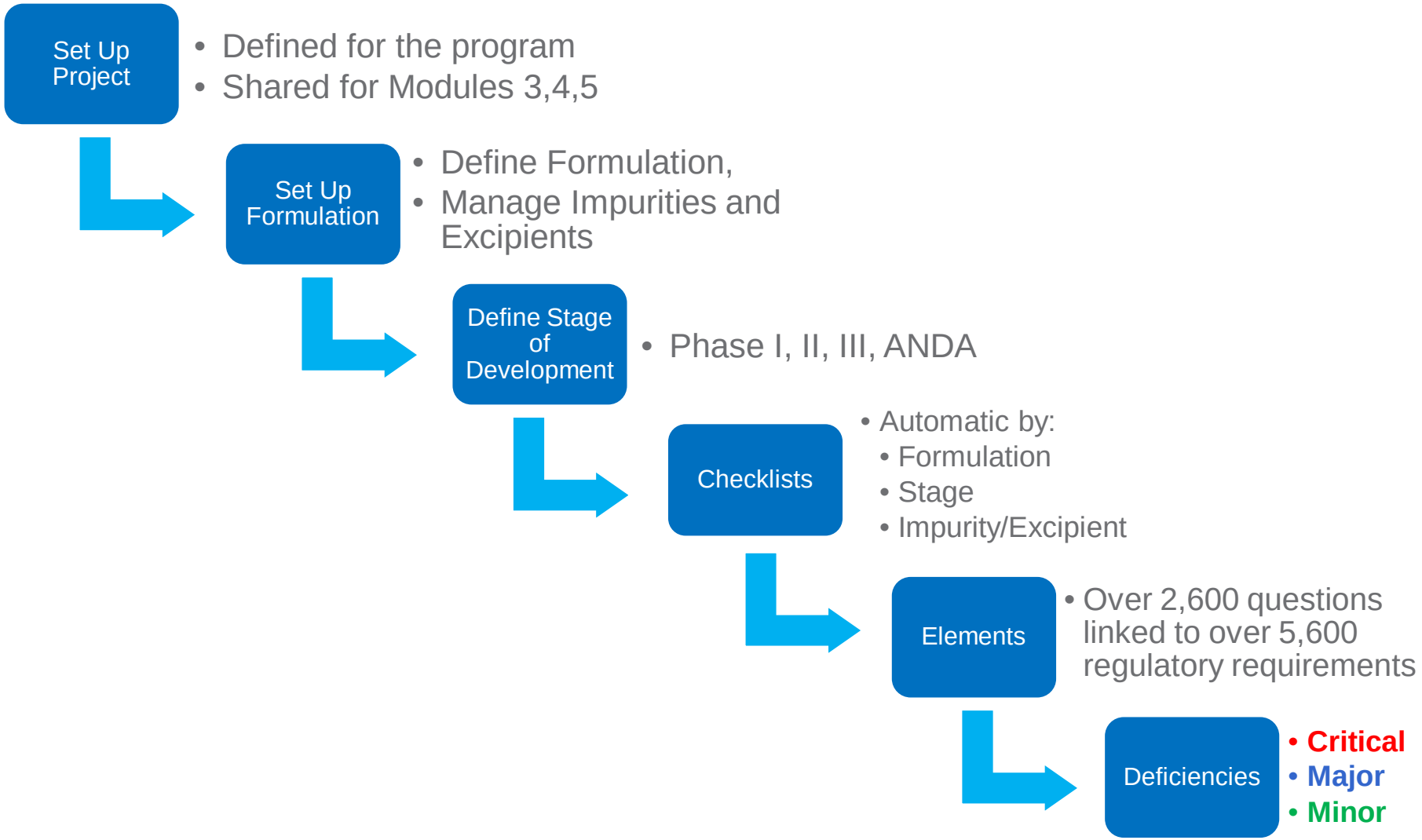
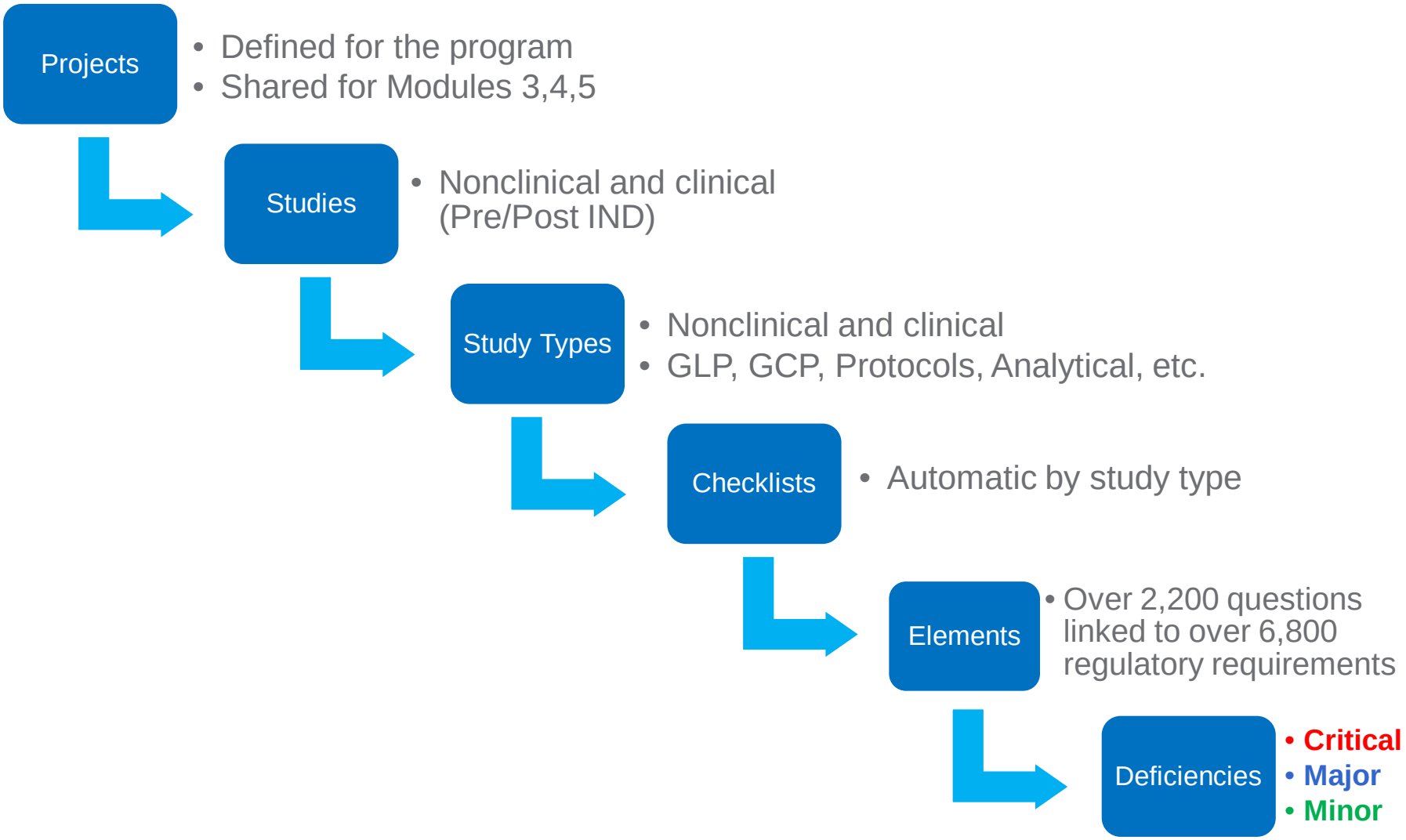
RegCheck™ Module 3 (CMC) Application Structure



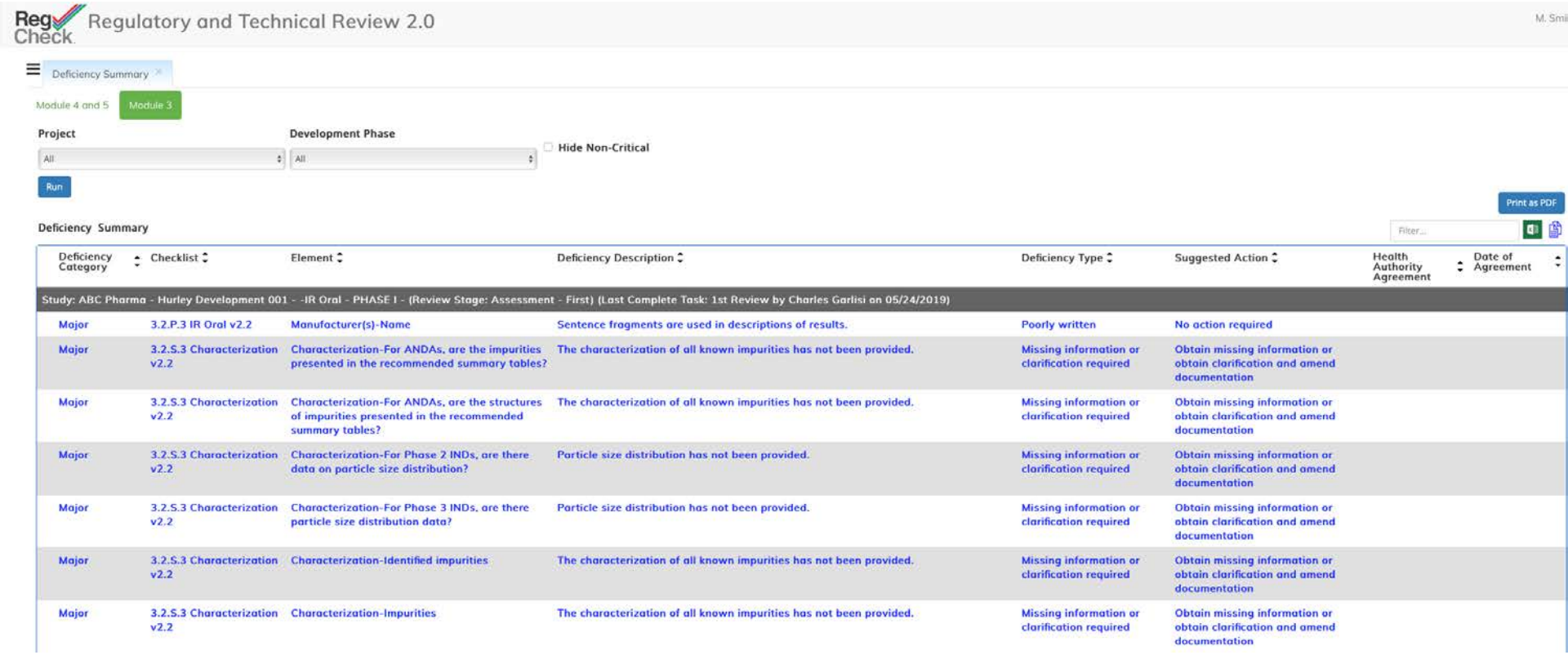
RegCheck™ Module 4&5 Application Structure



Deficiencies

- Critical deficiencies are those that affect the acceptability of the document or program to health authorities
- Major deficiencies are errors and problems that are significant but not sufficiently serious to affect the acceptability of the document or program
- Minor deficiencies are errors in text, tables, and figures, mostly related to editing and formatting that do not affect the acceptability of the document or program

Deficiency Summary: CMC Example



Deficiency Category	Checklist	Element	Deficiency Description	Deficiency Type	Suggested Action	Health Authority Agreement	Date of Agreement
Study: ABC Pharma - Hurley Development 001 - -IR Oral - PHASE I - (Review Stage: Assessment - First) (Last Complete Task: 1st Review by Charles Garlisi on 05/24/2019)							
Major	3.2.P.3 IR Oral v2.2	Manufacturer(s)-Name	Sentence fragments are used in descriptions of results.	Poorly written	No action required		
Major	3.2.S.3 Characterization v2.2	Characterization-For ANDAs, are the impurities presented in the recommended summary tables?	The characterization of all known impurities has not been provided.	Missing information or clarification required	Obtain missing information or obtain clarification and amend documentation		
Major	3.2.S.3 Characterization v2.2	Characterization-For ANDAs, are the structures of impurities presented in the recommended summary tables?	The characterization of all known impurities has not been provided.	Missing information or clarification required	Obtain missing information or obtain clarification and amend documentation		
Major	3.2.S.3 Characterization v2.2	Characterization-For Phase 2 INDs, are there data on particle size distribution?	Particle size distribution has not been provided.	Missing information or clarification required	Obtain missing information or obtain clarification and amend documentation		
Major	3.2.S.3 Characterization v2.2	Characterization-For Phase 3 INDs, are there particle size distribution data?	Particle size distribution has not been provided.	Missing information or clarification required	Obtain missing information or obtain clarification and amend documentation		
Major	3.2.S.3 Characterization v2.2	Characterization-Identified impurities	The characterization of all known impurities has not been provided.	Missing information or clarification required	Obtain missing information or obtain clarification and amend documentation		
Major	3.2.S.3 Characterization v2.2	Characterization-Impurities	The characterization of all known impurities has not been provided.	Missing information or clarification required	Obtain missing information or obtain clarification and amend documentation		

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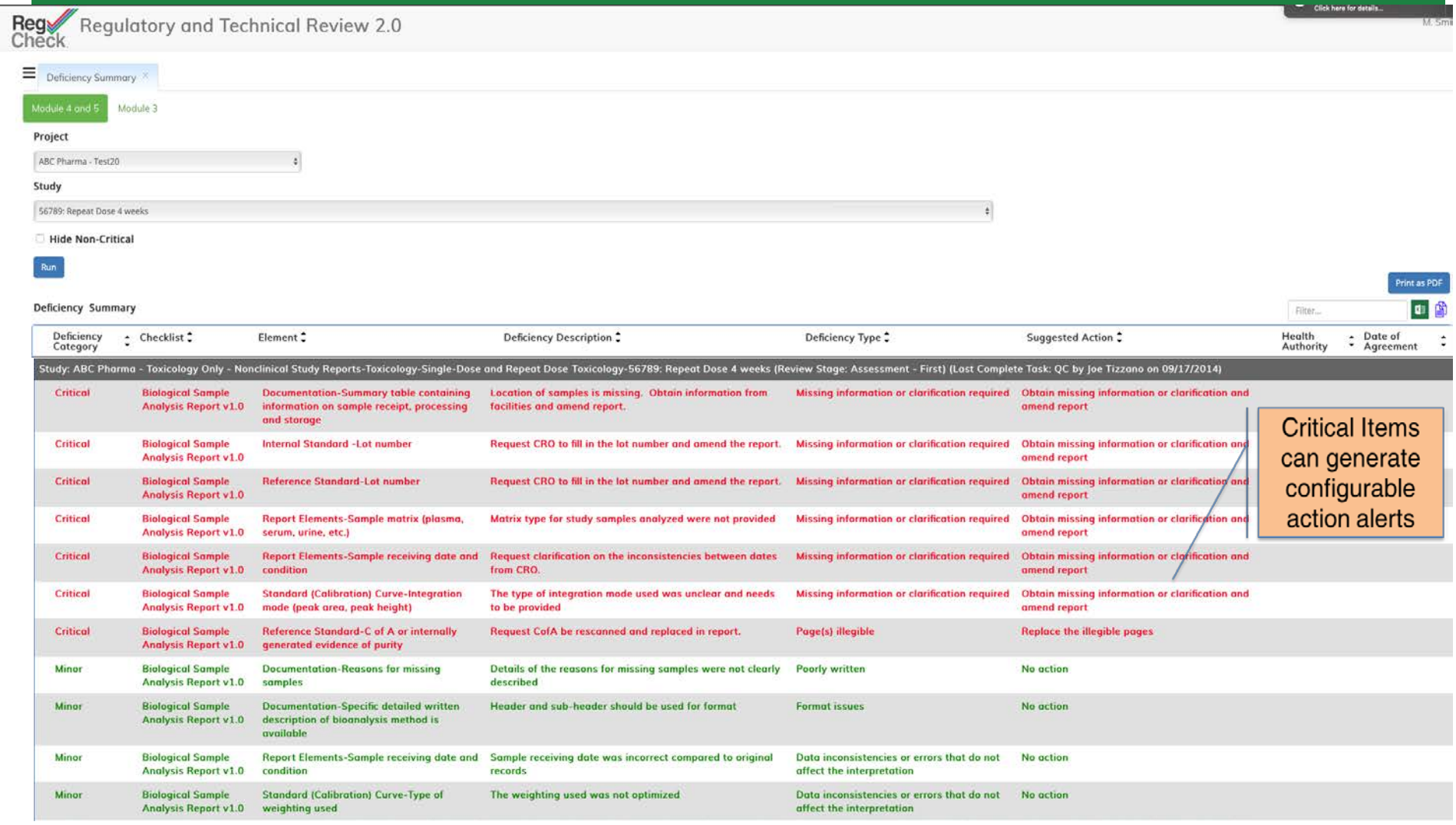
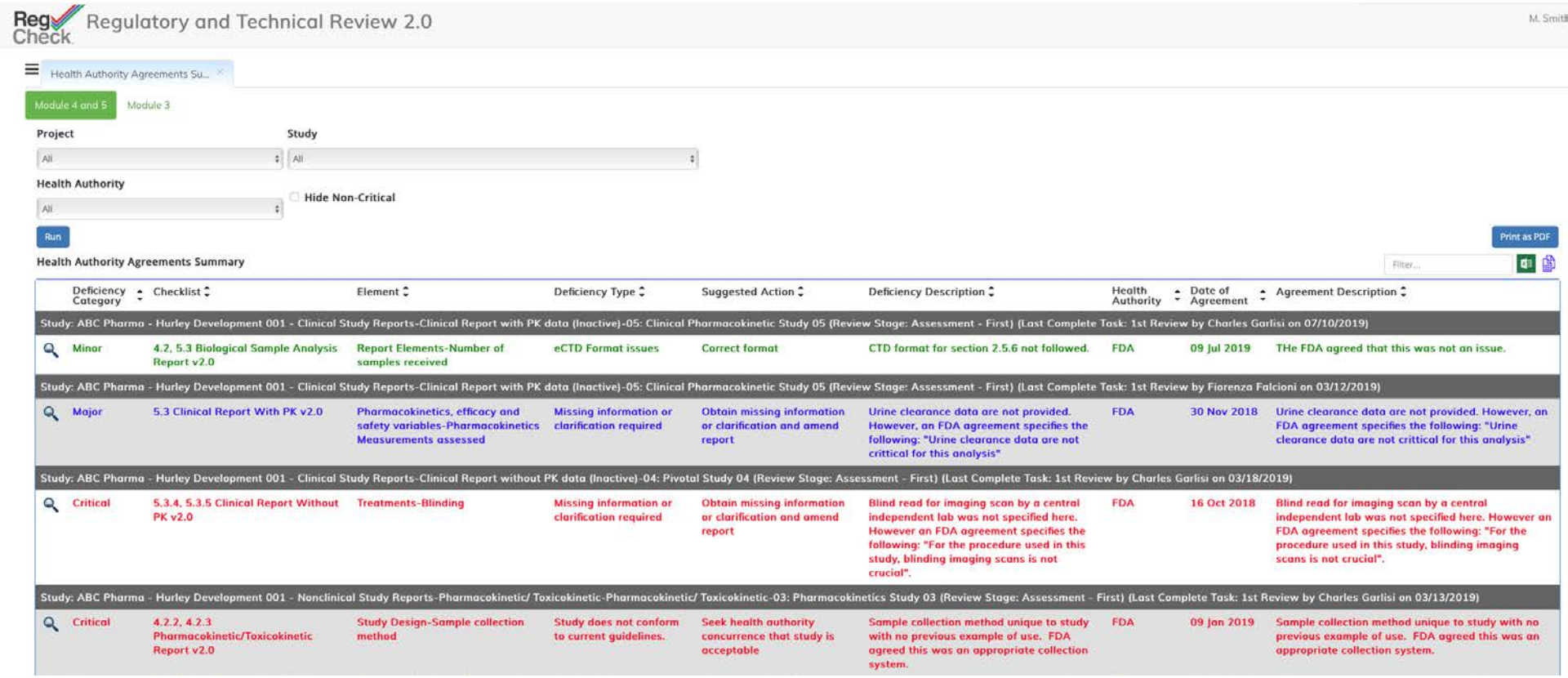
Deficiency Summary: GLP Study Example



- Example of a Deficiency Summary for a Toxicology Repeat-Dose study.

Health Authority Agreements



Deficiency Category	Checklist	Element	Deficiency Type	Suggested Action	Deficiency Description	Health Authority	Date of Agreement	Agreement Description
Study: ABC Pharma - Hurley Development 001 - Clinical Study Reports-Clinical Report with PK data (Inactive)-05: Clinical Pharmacokinetic Study 05 (Review Stage: Assessment - First) (Last Complete Task: 1st Review by Charles Garlisi on 07/10/2019)								
Minor	4.2, 5.3 Biological Sample Analysis Report v2.0	Report Elements-Number of samples received	eCTD Format issues	Correct format	CTD format for section 2.5.6 not followed.	FDA	09 Jul 2019	THe FDA agreed that this was not an issue.
Study: ABC Pharma - Hurley Development 001 - Clinical Study Reports-Clinical Report with PK data (Inactive)-05: Clinical Pharmacokinetic Study 05 (Review Stage: Assessment - First) (Last Complete Task: 1st Review by Fiorenza Falcioni on 03/12/2019)								
Major	5.3 Clinical Report With PK v2.0	Pharmacokinetics, efficacy and safety variables-Pharmacokinetics Measurements assessed	Missing information or clarification required	Obtain missing information or clarification and amend report	Urine clearance data are not provided. However, an FDA agreement specifies the following: "Urine clearance data are not crittical for this analysis"	FDA	30 Nov 2018	Urine clearance data are not provided. However, an FDA agreement specifies the following: "Urine clearance data are not crittical for this analysis"
Study: ABC Pharma - Hurley Development 001 - Clinical Study Reports-Clinical Report without PK data (Inactive)-04: Pivotal Study 04 (Review Stage: Assessment - First) (Last Complete Task: 1st Review by Charles Garlisi on 03/18/2019)								
Critical	5.3.4, 5.3.5 Clinical Report Without PK v2.0	Treatments-Blinding	Missing information or clarification required	Obtain missing information or clarification and amend report	Blind read for imaging scan by a central independent lab was not specified here. However an FDA agreement specifies the following: "For the procedure used in this study, blinding imaging scans is not crucial".	FDA	16 Oct 2018	Blind read for imaging scan by a central independent lab was not specified here. However an FDA agreement specifies the following: "For the procedure used in this study, blinding imaging scans is not crucial".
Study: ABC Pharma - Hurley Development 001 - Nonclinical Study Reports-Pharmacokinetic/ Toxicokinetic-Pharmacokinetic/ Toxicokinetic-03: Pharmacokinetics Study 03 (Review Stage: Assessment - First) (Last Complete Task: 1st Review by Charles Garlisi on 03/13/2019)								
Critical	4.2.2, 4.2.3 Pharmacokinetic/Toxicokinetic Report v2.0	Study Design-Sample collection method	Study does not conform to current guidelines.	Seek health authority concurrence that study is acceptable	Sample collection method unique to study with no previous example of use. FDA agreed this was an appropriate collection system.	FDA	09 Jan 2019	Sample collection method unique to study with no previous example of use. FDA agreed this was an appropriate collection system.