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

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…

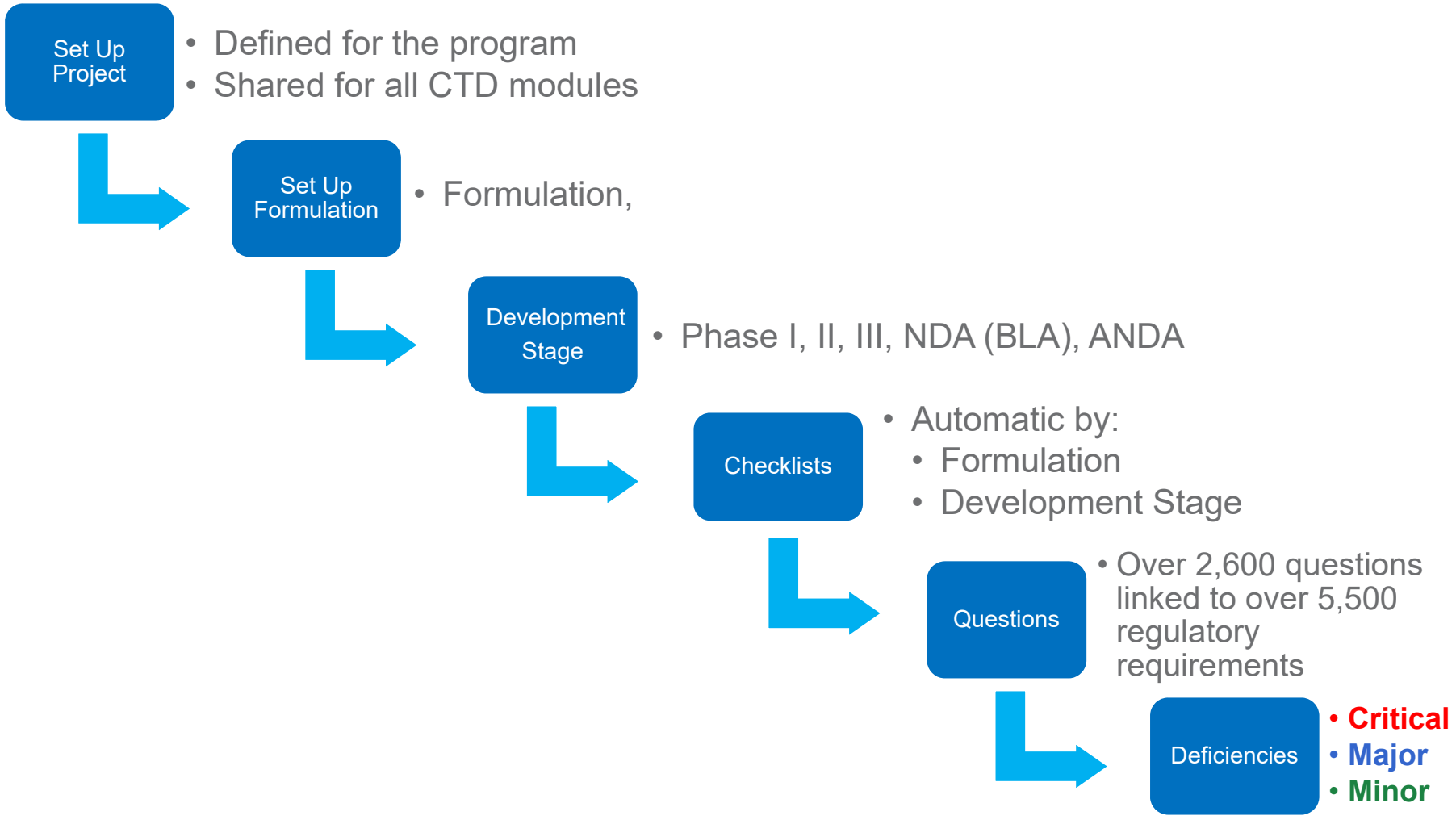
- 153 Checklists covering Modules 2, 3, 4 and 5
- Contains over 6,700 questions
- Linked to over 14,000 regulatory citations (21CFR and guidance documents)

Key Benefits

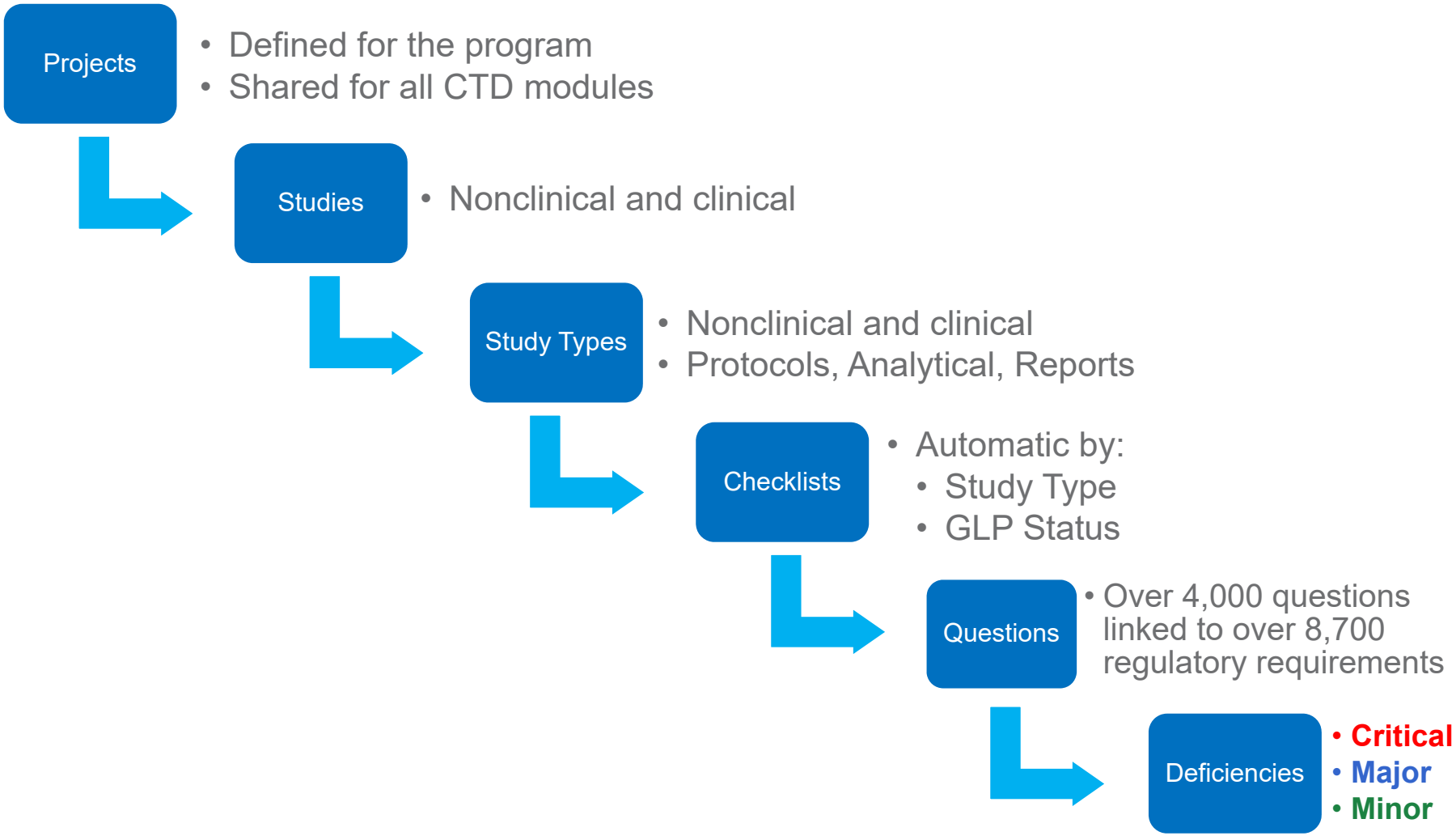
- Immediate access to specific regulatory requirements
- Identifies and prioritizes potential issues that could prolong or derail FDA review and approval
- Helps to avoid costly late-stage rework and potential delays in bringing a product to market
- Helps users evaluate deficiencies for products considered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

RegCheck

RegCheck™ Module 3 (CMC) Application Structure



RegCheck™ Module 2, 4, & 5 Application Structure



RegCheck

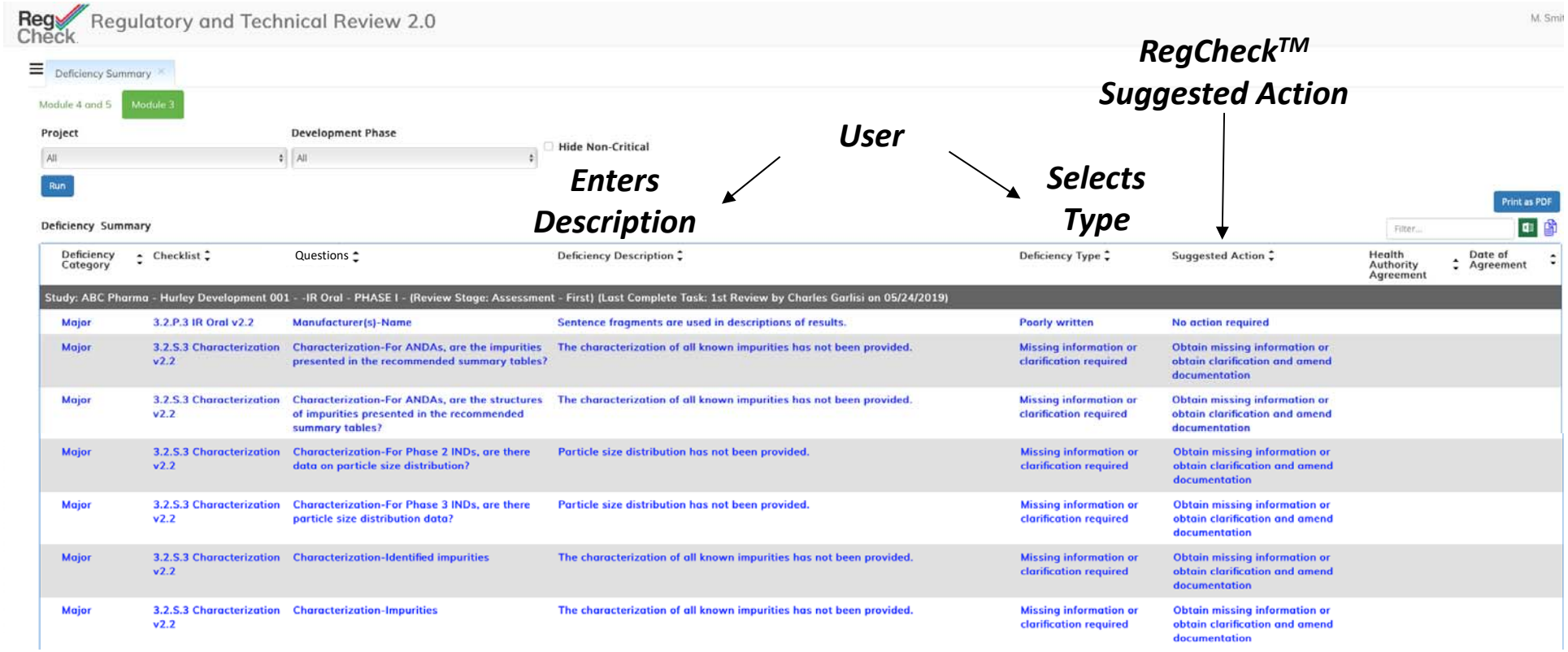
How Do You Work in RegCheck™?

- User enters the study information
- RegCheck™ assigns the appropriate checklists
- User answers the questions and for each deficiency, selects the deficiency type and enters the deficiency description
- RegCheck™ assigns the deficiency category and the suggested action

Deficiency Categories

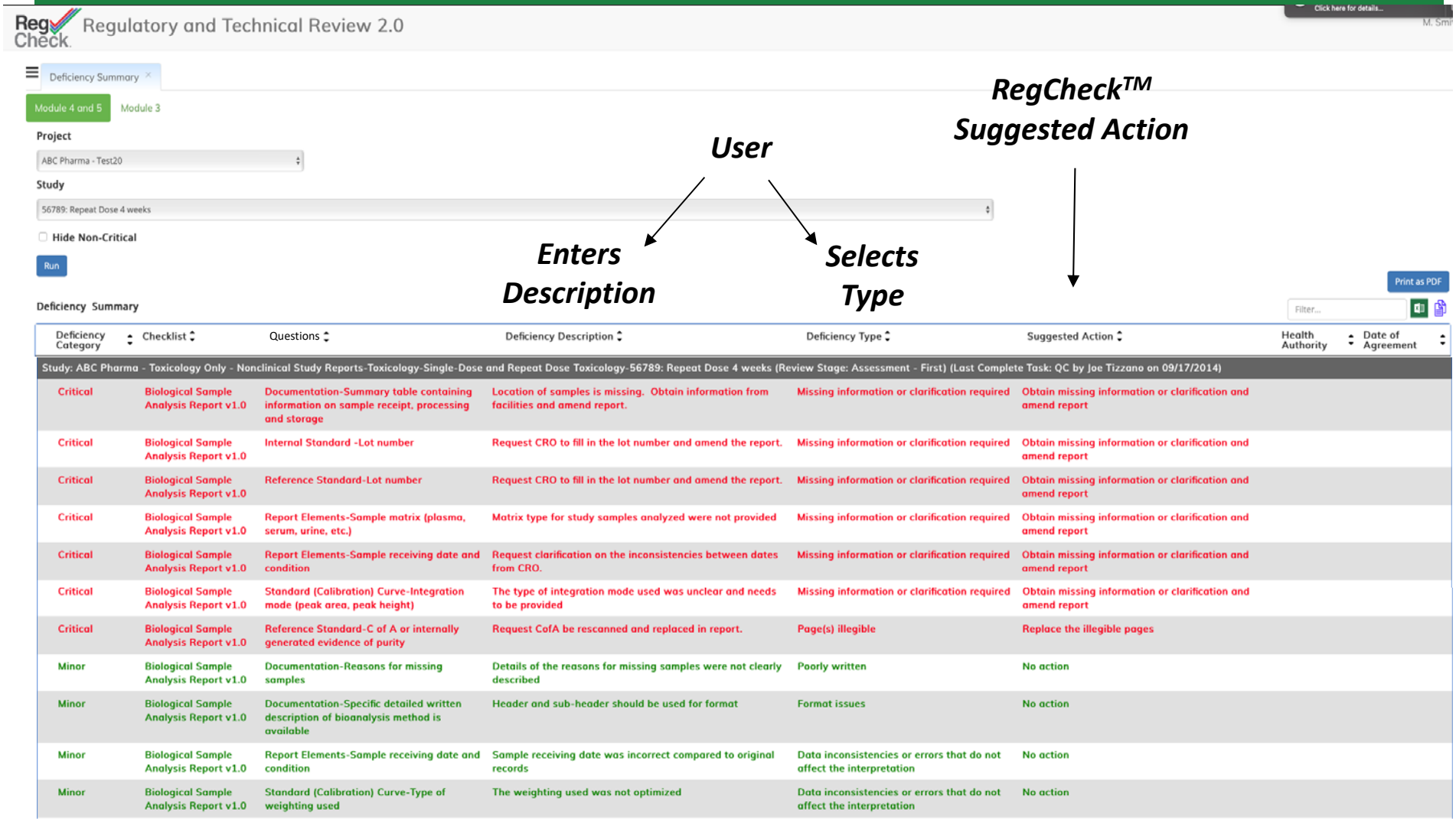
- Critical deficiencies are those that affect the acceptability of the document or program to health authorities
- Major deficiencies are errors and problems that are significant but not sufficiently serious to affect the acceptability of the document or program
- Minor deficiencies are errors in text, 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	Questions	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		

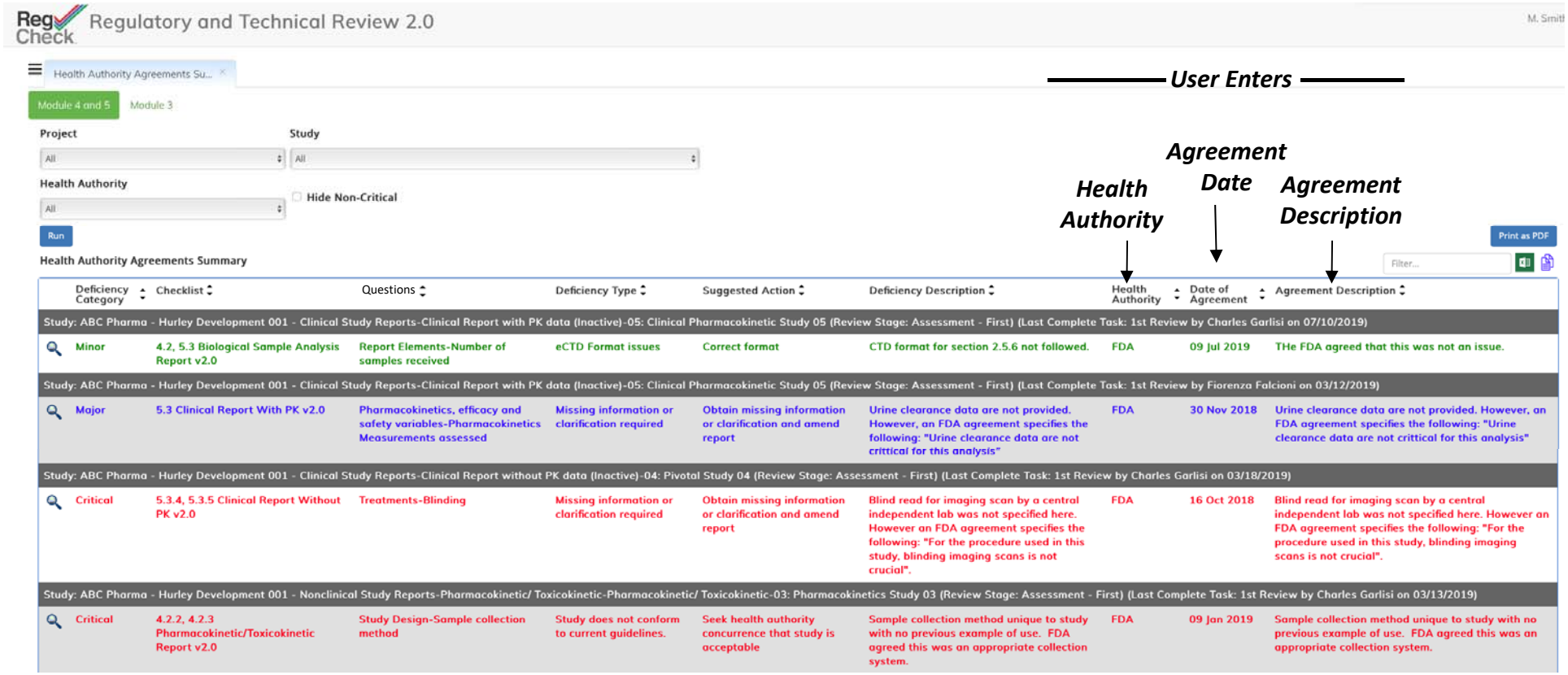
Deficiency Summary: GLP Study Example



Deficiency Category	Checklist	Questions	Deficiency Description	Deficiency Type	Suggested Action	Health Authority	Date of Agreement
Study: ABC Pharma - Toxicology Only - Nonclinical Study Reports-Toxicology-Single-Dose and Repeat Dose Toxicology-56789: Repeat Dose 4 weeks (Review Stage: Assessment - First) (Last Complete Task: QC by Joe Tizzano on 09/17/2014)							
Critical	Biological Sample Analysis Report v1.0	Documentation-Summary table containing information on sample receipt, processing and storage	Location of samples is missing. Obtain information from facilities and amend report.	Missing information or clarification required	Obtain missing information or clarification and amend report		
Critical	Biological Sample Analysis Report v1.0	Internal Standard -Lot number	Request CRO to fill in the lot number and amend the report.	Missing information or clarification required	Obtain missing information or clarification and amend report		
Critical	Biological Sample Analysis Report v1.0	Reference Standard-Lot number	Request CRO to fill in the lot number and amend the report.	Missing information or clarification required	Obtain missing information or clarification and amend report		
Critical	Biological Sample Analysis Report v1.0	Report Elements-Sample matrix (plasma, serum, urine, etc.)	Matrix type for study samples analyzed were not provided	Missing information or clarification required	Obtain missing information or clarification and amend report		
Critical	Biological Sample Analysis Report v1.0	Report Elements-Sample receiving date and condition	Request clarification on the inconsistencies between dates from CRO.	Missing information or clarification required	Obtain missing information or clarification and amend report		
Critical	Biological Sample Analysis Report v1.0	Standard (Calibration) Curve-Integration mode (peak area, peak height)	The type of integration mode used was unclear and needs to be provided	Missing information or clarification required	Obtain missing information or clarification and amend report		
Critical	Biological Sample Analysis Report v1.0	Reference Standard-C of A or internally generated evidence of purity	Request CofA be rescanned and replaced in report.	Page(s) illegible	Replace the illegible pages		
Minor	Biological Sample Analysis Report v1.0	Documentation-Reasons for missing samples	Details of the reasons for missing samples were not clearly described	Poorly written	No action		
Minor	Biological Sample Analysis Report v1.0	Documentation-Specific detailed written description of bioanalysis method is available	Header and sub-header should be used for format	Format issues	No action		
Minor	Biological Sample Analysis Report v1.0	Report Elements-Sample receiving date and condition	Sample receiving date was incorrect compared to original records	Data inconsistencies or errors that do not affect the interpretation	No action		
Minor	Biological Sample Analysis Report v1.0	Standard (Calibration) Curve-Type of weighting used	The weighting used was not optimized	Data inconsistencies or errors that do not affect the interpretation	No action		

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

Health Authority Agreements



Sponsor Options

- License RegCheck™
- Hurley Consulting performs RegCheck™ review and provides the reports to the sponsor

Demonstration

Please contact

info@myregcheck.com