

RQAP-GMP Examination Detailed Content Outline

The scored items on the exam are comprised of the sections in the following table, with the number of exam items in each section corresponding to the score percentage in the right column.

A. Approving or Rejecting Components, Materials, and Finished Products	18%
1. Establish and approve specifications for components, materials, and finished products	
2. Conduct supplier/vendor qualifications	
3. Quarantine materials and components prior to inspection or testing	
4. Inspect or test incoming components and materials	
5. Inspect or test in-process products	
6. Inspect or test finished products	
7. Ensure traceability and chain of custody for incoming components/materials and final products	
B. Approving or Rejecting Procedures	24%
1. Identify appropriate regulatory requirements	
2. Identify list of SOPs to be created	
3. Create governing SOP for SOPs	
4. Collaborate with SMEs on writing SOPs	
5. Review and approve SOPs	
6. Develop training materials on SOPs	
7. Train staff on SOPs	
8. Implement effective SOPs	
9. Conduct periodic review of SOPs	
C. Conducting Investigations	18%
1. Initiate investigation	
2. Gather and collect initial facts	
3. Determine root cause	
4. Conduct impact analysis	
5. Identify corrective and preventive action (CAPA)	
6. Perform effectiveness check	
7. Conduct trending analysis	
D. Creating and Monitoring the QMS	40%
1. Build the QMS	
2. Implement the QMS	

3. Establish KPIs	
4. Conduct management review	
5. Conduct internal audits	
6. Conduct external audits	
7. Conduct change control	
8. Conduct complaint process	
9. Conduct recall process	
10. Apply continuous improvement	