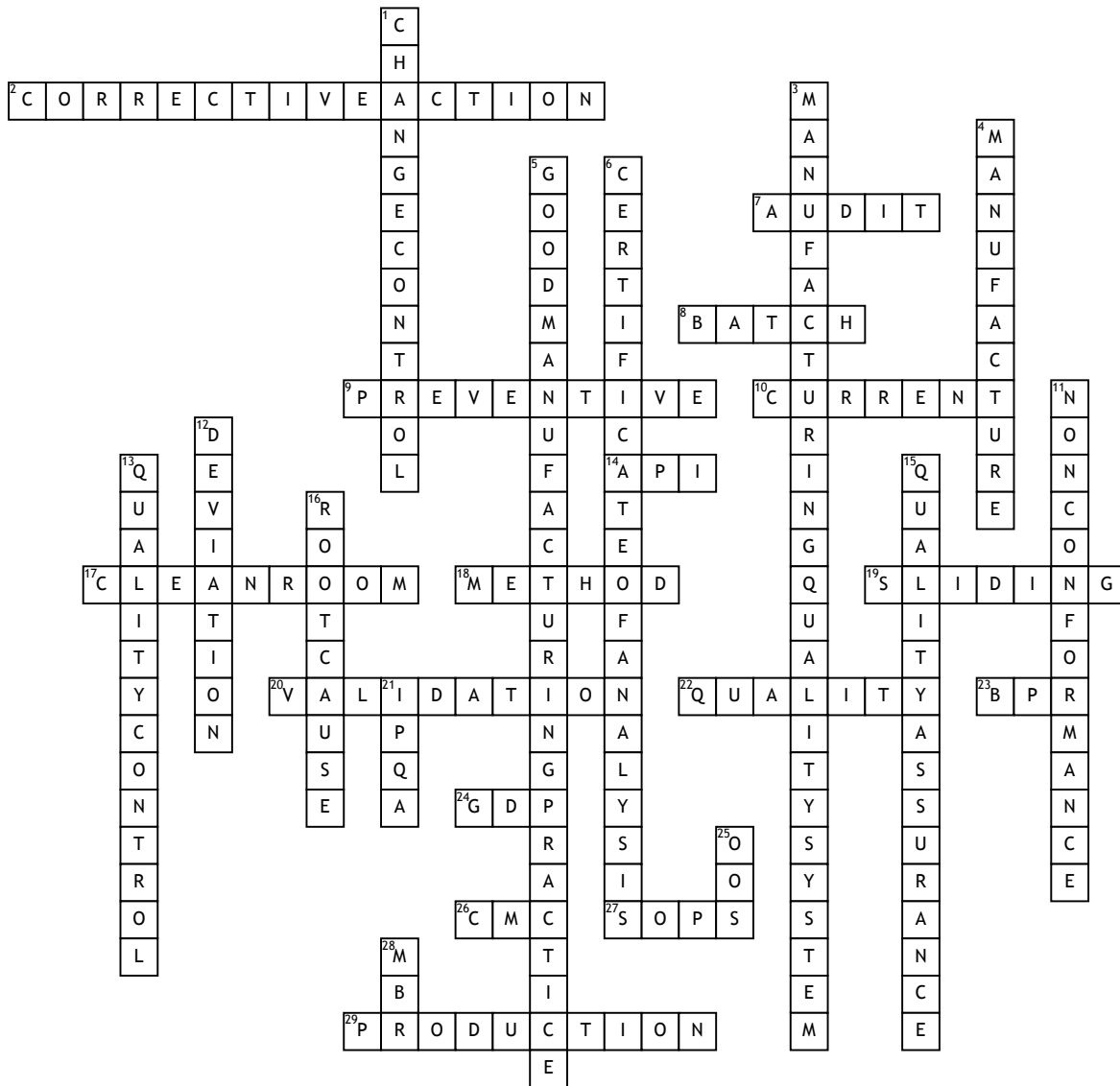


Good Manufacturing Practice (GMP)



Across

2. A solution meant to reduce or eliminate the cause of a detected nonconformity or other undesirable situation
7. An inspection to check for GMP compliance
8. A specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture. (21 CFR 210.3)
9. An action taken to remove or improve a process to prevent potential future occurrences of a nonconformance
10. The "c" in cGMP stands for "_____" reminding manufacturers that they must employ technologies and systems which are up-to-date in order to comply with the regulation
14. Any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product
17. An environment, typically used in manufacturing, that has a controlled level of contamination that is specified by the number of particles per cubic meter at a specified particle size
18. _____ validation is the process by which it is established, by laboratory studies, that the performance characteristics of the analytical methods meet the requirements for the intended application
19. The FDA applies cGMP regulations on a _____ scale.
20. Action of proving, in accordance with the principles of GMP, that any procedure, process, equipment, material, activity or system actually leads to the expected results

22. The suitability of either a drug substance or drug product for its intended use. This term includes such attributes as the identity, strength, and purity.

23. The document used for each individual batch of API, based on the master production instruction

24. A practice that ensures concision, legibility, accuracy, authenticity, and traceability of all development, production, and testing activity records

26. A section in an Investigational New Drug (IND) application describing the composition, production, and controls of the drug substance and product (21 CFR 312.23(a)(7))

27. A set of step-by-step instructions compiled by an organization to help workers carry out complex routine operations

29. All operations involved in the preparation of a product, from receipt of materials,

Down

1. A formal monitoring system by which qualified representatives of appropriate disciplines review proposed or actual changes that might affect the validation status of a system or process and cause corrective action, if any, to be taken that will ensure that the system or process retains, or is placed back into a validated state of control

3. A hierarchical set of MSK policies and procedures, documented in SOP format, describing institutional cGMP compliance

4. All operations of purchase of materials and products, Production, Quality Control, release, storage, distribution of products and the related controls

5. A system for ensuring that products are consistently produced and controlled according to quality standards, designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product

6. A document issued by QA that confirms that a product meets its specification.

11. The non-fulfilment of a specified "material/product" requirement - (usually to a specification) that usually leads to rejection or reworking of the item

12. A departure from standard procedures or specifications resulting in non-conforming material &/or processes, or where there have been unusual or unexplained events which have the potential to impact on product quality, system integrity or personal safety

13. One of the functions of this group is to accept or reject each batch or lot based on review of the completed manufacturing records

15. Planned and systematic activities implemented in a quality system so that quality requirements for a product will be fulfilled

16. The basic cause of a deviation, from which effective actions can be defined to prevent recurrence

21. This group's mission is to ensure "quality and efficiency, while supporting regulatory compliance, in the development and manufacture of clinical trial investigational products at MSK

25. A finished product or raw material test result that falls outside approved, registered or official specifications or acceptance criteria. If validated it results in a Non-conforming product.

28. Version controlled templates or instructions for the manufacturing process