TOXIN MEDICAL COUNTERMEASURES - DEVELOPMENT OF NOVEL, BROAD-SPECTRUM COUNTERMEASURES FOR TOXIN EXPOSURE

Testing And Evaluation Of Synthesized Peptide Proteins Using Quality Metrics

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Chemical synthesis and in vitro folding of peptides can lead to products that contain large amounts of inactive material, the proportion of which varies from lot to lot. These variations can impact research as the consistency of results commonly correlates with the quality of the material under study. Further complicating matters for researchers, the suppliers for these peptides of interest tend to be small operations with unknown quality control processes, and many are located OCONUS. To mitigate these inconsistencies, DEVCOM Chemical Biological Center (CBC) has developed a program to document, produce, and characterize synthetic lots of peptide toxin using standards and practices for testing under CBC's established Quality program. Focusing on Quality metrics, CBC implemented inventories that include equipment identification, vendor and suppliers, and material receipt and tracking which culminates in an all-inclusive quality document master list. These lists capture and record the metrics of all equipment and material required for the standardization and reproducibility of synthesized peptide toxin lots. Furthermore, operating procedures for the equipment as well as the establishment of test methods bolster and drive a standardized system while still allowing documented deviations that occur in research settings. All material produced is subjected to testing under approved specifications that examines sample purity and activity. Product shelf-life is also evaluated to ensure that material does not have a significant loss of activity over time and is a predicter to expiration dating. Lastly, a shipping study outlines how the material is packaged and shipped during diverse temperature conditions (30◦F and 90◦F) to assess the effects of temperature on the purity and activity of a toxin sample. This allows for a better understanding of the stability of the material during transit. Production and testing under quality type documentation and material tracking enables the standardization across facilities ensuring consistencies in quality and performance of the material between producers. Establishing quality metrics and documentation facilitates transition where all producers can synthesize and test material resulting in the same analytical result and performance.

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