

8<sup>th</sup> International Conference and Exhibition on

# Pharmaceutical Regulatory Affairs and IPR

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# Pharma Audit, GMP, GCP & Quality Control

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## Joe Helmstetter

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### Investigations, root cause analysis, corrective & preventive actions and why “human error” is not the true root of the problem

Proper Root Cause Analysis (RCA) is essential to ensure the implementation of Corrective & Preventive Actions (CAPA). A poorly executed RCA can lead to incorrect and ineffective CAPAs, which leads to repeated failures. Any event requiring RCA and CAPA is an opportunity for improvement, not only related to the original event but also in relation to any quality or compliance issues discovered during the investigation. Some estimates state that 80% of adverse events are due to human error. This could not be further from the truth. Commonly, root causes that are attributed to human error are incomplete investigations/RCAs as one must go beyond human error to discover the true root cause.

### Biography

Joe Helmstetter is a dedicated problem solver, status quo challenger and change-maker who's aim is to simplify and streamline processes/systems/procedures while ensuring greater quality, compliance and accuracy of output. He has 15 years of experience in the pharmaceutical industry with expertise in building and rebuilding quality systems for increased compliance and a more efficient and effective Quality Unit. Much of the time these changes can be made in response to the results of investigations and/or root cause analysis results and executed along with other corrective & preventative actions.

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### Notes: