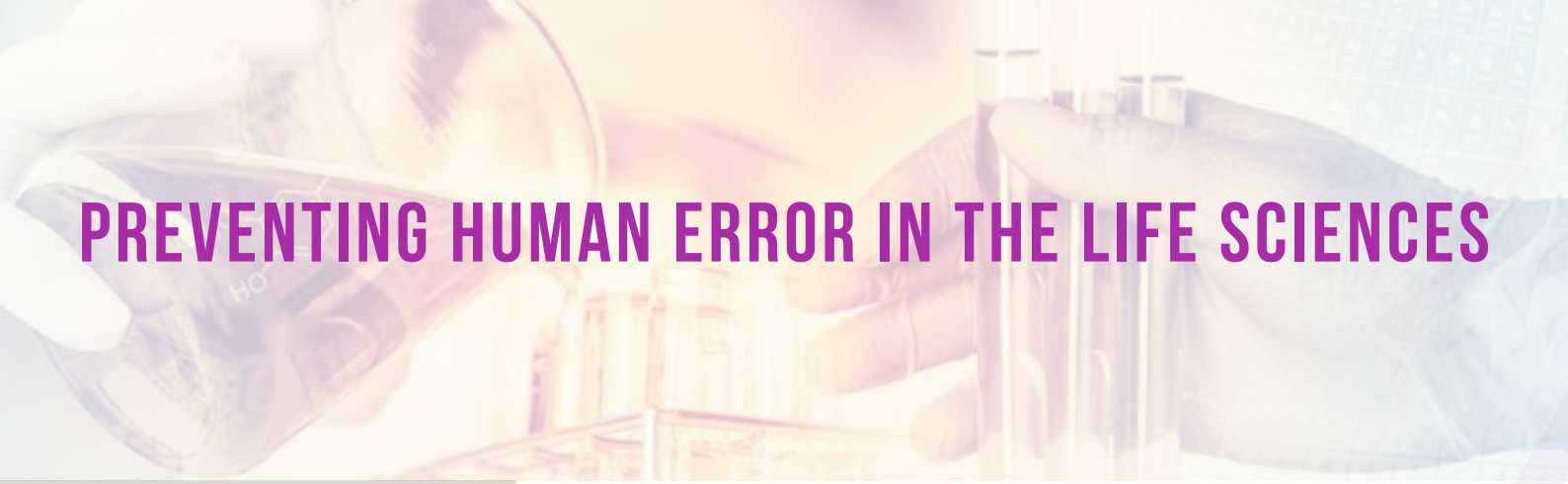

PREVENTING HUMAN ERROR IN THE LIFE SCIENCES

WHO WILL BENEFIT

This virtual seminar will benefit everyone in the life sciences who works within the manufacturing, engineering, quality, and regulatory functions or services to include, machine operators and mechanics, quality assurance, technical services, laboratory, regulatory, engineers, documentation development and management with titles such as associates, technicians, scientists, supervisors, managers, and directors.

FACULTY
CHARLES H. PAUL

Charles H. Paul is the President of C. H. Paul Consulting, Inc. – a regulatory, training, and technical documentation consulting firm. Charles has been a regulatory consultant for over 20 years and has published numerous white papers on the subject. The firm works with both domestic and international clients designing solutions for complex training and documentation issues.

OVERVIEW

It would be terrific if the human error we or others exhibit only resulted in minor problems and issues that were easily dealt with but that is simply not the case. The consequences of human error run the gamut from minor to severe, sometimes resulting in the death of the performer and others at the extreme.

The potential for human error exists in every system with which we interact. No amount of automation, documentation, or mistake-proofing cannot entirely eliminate the potential for human error. It simply requires the alignment of the right combination of consequences for the error to occur.

This eight-hour 4-hour per day virtual seminar, will explore the true causes and nature of human error, how human error should be investigated, how human error relates to human performance, the aspects of human error that will collapse your manufacturing operations, and the difference between real human error and systems, processes, and management deficiencies.

WHY SHOULD YOU ATTEND

Human Error occurs in all settings. Human Error frequently occurs in pharmaceutical manufacturing, even when the organization has done everything possible to prevent its occurrence. Documentation appears accurate, personnel are fully trained and equipment operates as designed; but errors continue to be made. Why? That is what we will explore in this seminar.

In the world of pharmaceutical manufacturing, the result of human error can result in loss of product or at the most extreme, injury to patients.

In many organizations, 'Human Error' is determined as the root cause of the event with reasons assigned such as 'lack of attention to detail' or 'failure to follow procedure'. Corrective action usually involves re-training or disciplinary action. Such approaches do not seek to understand why the error(s) occurred in the first place and they certainly cannot be expected to prevent re-occurrence.

The human error problem can be viewed in two ways: the human approach and the system approach. Each has its model of error causation and each model gives rise to quite different philosophies of error management. Understanding these differences has important practical implications for coping with the ever-present risk of mishaps in pharmaceutical manufacturing.

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AGENDA

Section #1 – The basics of human error

- Discussion of Human Error – what it is and what it is not.
- The regulatory considerations surrounding human error
- Nature of human error in pharmaceutical manufacturing?
- What kinds of errors, problems, or issues occur in the plant?
- How did we think about and respond to human error in the past?
- How should we address human error today given what we know about human performance?
- What changed that thinking? – DOE – Department of Energy
- *Exercise #1 – Types of human error experienced/observed*
- How does human error impact regulated industries?
- Human performance
- What is the relationship between human error and human performance?
- The guiding principles of human error
- People's performance is shaped by their capabilities and limitations.
- People interpret situations differently and perform in ways that make sense to them.
- People adapt to meet the demands of a complex and dynamic work environment.
- People assess risks and make trade-offs.
- People's performance is influenced by working with other people, technology, and the environment.

Section #2 – Categorizing Human Error

- Aligning the holes in the Swiss cheese
- The contributors to human error
- Error categories
- Skill-based
- Knowledge-based
- Rule-based
- The human error model
- Active and latent error what are the differences and why are they important

Section #3 – Anatomy of an error

- Line clearance example
- The stage is set for the error to occur
- What are the people issues?
- What are hotspots?
- Handling Line Clearance failures
- *Exercise #2 – What are the elements of this error?*

Section #4 – Human Performance and Human Error

- What is human performance?
- What are the factors that shape human performance?
- What do adults need to perform effectively?
- 6-cell performance engineering model

Summary and Questions

Section #5 – Human Error Prevention Tools

- Human performance tools
- Pre-work briefing
- Two-minute rule
- Three-way communication
- Communication behaviors to emulate
- Phonetic alphabet
- Procedure use
- Place-keeping
- Flagging and operational Barriers
- Self-Checking
- Independent verification
- Concurrent verification
- Stop when unsure
- Peer checking
- Exercise #3 – Applying human error prevention tools

Section #6 – Identifying Human Error

- Introduction to error traps
- Individual error traps
- Organizational error traps
- Human nature error traps
- Process error traps
- Physical environment error traps
- Mental biases
- Role of training and documentation
- Relationship between human performance and training
- Read and understand and why it is bad
- Eliminating the root causes of errors
- The role of documentation and User Support Tools in preventing human error

Section #7 – The role of CAPA in Human Error Identification and Future Prevention

- CAPA and risk management
- Tackling the problem of human error
- Human error reduction and mitigation techniques
- Exercise #4 – Identifying root causes

Section #8 – Human Error Prevention and Mitigation Options

- Application errors
- Decision errors
- Omission errors
- Learning gap errors
- Memory Gap errors
- Mistake Proofing

Summary and Questions

Preventing Human Error in the Life Sciences

REGISTRATION FORM

Name _____ Email _____

Organization _____ Department _____ Position _____

Phone _____ Mobile _____

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Terms And Condition

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- Cancellation of participant/s shall be submitted in writing to WCS ten days (10 days) before the course. There is a 50% liability on all bookings once made.
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