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Human Heuristics: Understanding the Impacts for Pharmaceutical Quality Risk Management

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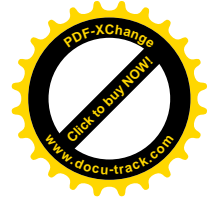
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Human Heuristics Understanding the impacts

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Delivering Cost Effective GMP Solutions

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Risk Management & Uncertainty

- A core principle underpinning effective Risk Management is the principle that Risk Management explicitly addresses *uncertainty* i.e., that it explicitly takes account of uncertainty, the nature of that uncertainty, and how it can be addressed *

*Ref : ISO 31000:2009(E)



Human Heuristics

- Heuristics are *cognitive behaviours*
- They come into play when we make *judgments in the presence of uncertainty*
- How these behaviours are manifested is still the subject of much research, but there is much evidence in the literature that heuristics are a *source of significant bias and errors in judgment*
- *Awareness of the potential adverse influences* of human heuristics on the outcomes of QRM exercises, e.g., during brainstorming and other team-based decision-making activities is key to designing and implementing your QRM tools successfully



Source: Practical Strategies for Improving Quality Risk Management activities in GMP environments - K.O'Donnell/ISPE's QRM Conference, Frankfurt, April 2011

Human Heuristics

- *How to deal with the Heuristic of Anchoring & Adjustment?*
- *How to deal with the Heuristic of Availability?*
- *How to deal with the Heuristic of Representativeness?*
- Practical strategies can be developed in relation to each of the problems listed above!

Source: Practical Strategies for Improving Quality Risk Management activities in GMP environments - K.O'Donnell/ISPE's QRM Conference, Frankfurt, April 2011



Anchoring and Adjustment:

- When this heuristic is in operation, people's judgement can be heavily influenced by the first approximation of the value or quantity that they think of or hear.
- This first approximation is termed an 'anchor' in the person's thought process, and this value is known to influence any subsequent adjusted values for the quantity in question that are estimated.
- Research by Kahneman and Tversky has demonstrated that the value of this anchor is critical

Availability

- This heuristic affects how people *estimate the probability* of an event occurring.
- A person's probability judgement is often determined by "the ease with which people can *think of previous occurrences* of the event", or the ease with which they *can imagine the event occurring*
- This can cause people to sometimes *over-estimate the frequency* of an event where recall or imagination are enhanced, and to *under-estimate the frequency* of an event where recall or imagination are difficult.
- In contrast, people tend to make *reasonable estimates* of event frequencies *when their experience and memory of observed events* corresponds fairly well with actual frequencies

Representativeness

- This heuristic also affects how people estimate the probability of an event occurring but also may affect how appropriate risk mitigation strategies are arrived at
- A person's probability judgement is often influenced by one "expecting in the small behaviour that which one knows exists in the large"
- When this heuristic is in operation, people *can pay too much attention to the specific details*, while ignoring or *paying insufficient attention to important background information* that is relevant to the problem at hand.
- Research has shown that people tend to ignore or forget important probability-related information when they have been given other specific information which is worthless to the question at hand

Risk Perception

Risk perception issues can also lead to *subjectivity and uncertainty* in the outcomes of Quality Risk Management exercises

ICH Q9 states, "each stakeholder might perceive different potential harms, place a different probability on each harm occurring and attribute different severities to each harm"

Risk Communication

- Stakeholders form judgements about risks based on their own perceptions of those risks
- It is important, therefore, to ensure that the risks that are identified for the process or item under study are *communicated* to decision makers, stakeholders and other interested parties in a way that *minimises problems of mis-perception*.

Risk Communication

- It promote a *culture of risk awareness* within the organisation and it may actually help to reduce risks.
- Research by Kaplan and Garrick in 1981 demonstrated that risk awareness is an *important safeguard* that may actually *help to reduce risks*

Some Useful References

- O'Donnell, K., *Strategies for Addressing the Problems of Subjectivity and Uncertainty in Quality Risk Management Exercises: Part I* — The Role of Human Heuristics, Journal of Validation Technology, Vol. 16, No. 3, Summer 2010
- O'Donnell, K., *Strategies for Addressing the Problems of Subjectivity and Uncertainty in Quality Risk Management Exercises: Part II* — Risk Communication and Perception, Journal of Validation Technology, Vol. 16, No. 4, Autumn 2010

Thank You for your Time



Any Questions?