

WELCOME

**TPD-CVG Convention 2003
September 25 & 26, 2003
Toronto, Canada**

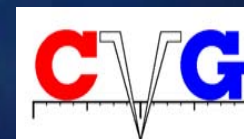
**“Challenges to Analytical and
Formulation Scientists: Scientific and
Regulatory Perspectives”**



Health
Canada

Santé
Canada

Therapeutic Products Directorate
Direction des produits thérapeutiques



Calibration & Validation Group

“What if.....”

- ❖ Some of the “what if”s have the property of an imaginary number (i)!

$$i^2 = -1$$

$$(\text{What if})^2 = \text{negative}$$

- ❖ Imaginative pessimism stifles real creativity and innovations

Risks

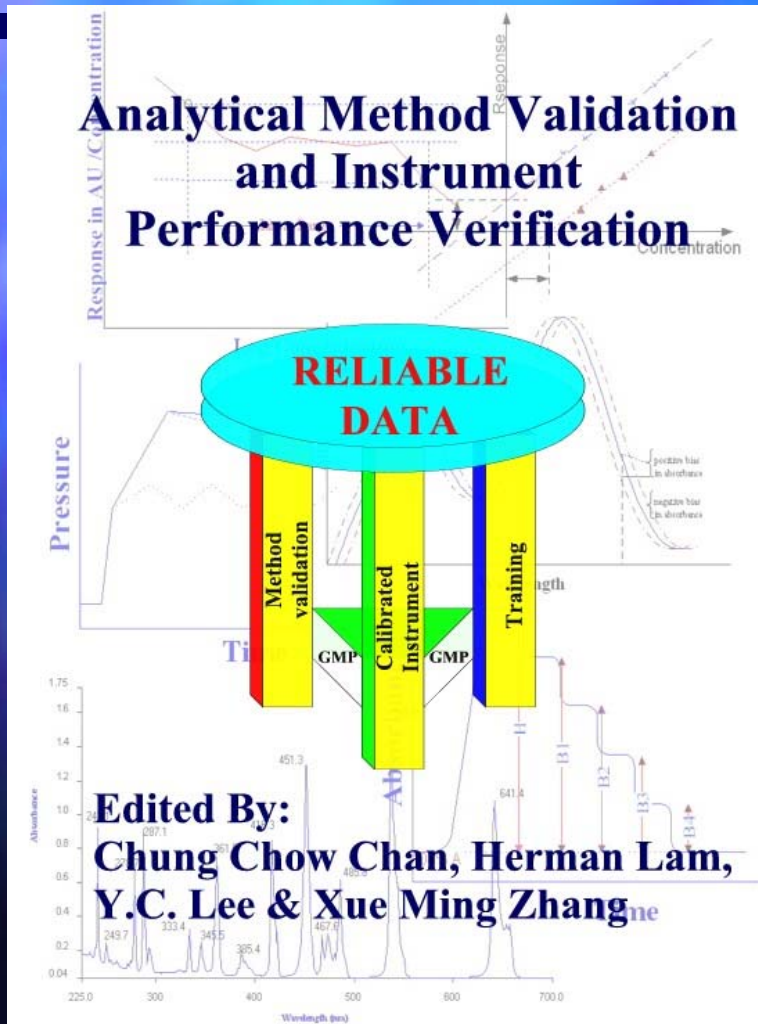
- ❖ $RISK = Severity \times Likelihood$
- ❖ There are risks for trying to be risk-free!

Right Decisions

- ❖ Based on knowledge and experiences

"The work should be performed according to thy needs, no more no less".

CVG Book



ANALYTICAL METHOD VALIDATION AND INSTRUMENT PERFORMANCE VERIFICATION

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