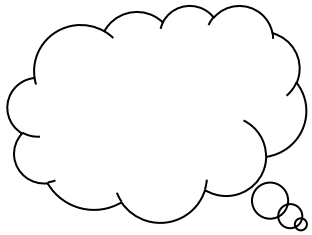

Have you experienced **prolonged discussions** with your local FSA ?
Have you wondered why ?
We often **fail** to communicate what's **important**

- Discussions which often are followed by even longer Q&A's – the approval process lingers on
- Many times we wonder why this is ?
  - Could it be the way we engage the regulator ?
  - Could we build a better relationship with the regulator ?
  - Should we be more active in our dealings with the regulator ?
- **Possibly** you should. But a better relationship hardly lets you slip in a lower calibration for a rating model. A better relationship hardly puts you in the free from the long list of questions you usually get
- Perhaps it time for you to **change ?**
- Perhaps you should try and change which information and knowledge you share in your model documentation instead – **connect and learn** from other industries
- Some years ago the American Pharmaceutical industry was facing similar issues with their interaction with FDA. One of the solutions to shorter approval process was '**Quality by Design'**
- 'Quality by Design' is a way to work which helps you in addressing the most **important** things in your application for a new model or drug

Increase your focus on what you actually communicate – **FSAs** spend hours after hours on reading your documentation and **only a few** in meetings with you

Current Approach	QbD Approach
Quality assured by testing, inspection and further away explanations	**Quality** built into product & process by design, based on product and customer understanding
Data intensive submission – disjointed information **without "big picture"**	**Knowledge rich** submission – showing product knowledge & process understanding
Specifications based on retrieval of historic information	Specifications based on **customers needs** and product performance requirements
"Frozen process," discouraging changes – modeling process purely focused on data extraction and getting the models approved	Flexible process within design space, allowing **continuous improvement**
Focus on reproducibility – often avoiding or **ignoring variation**	Focus on **robustness** – understanding and controlling variation