US National Quality Standard for Biomedical Research

ASQ Food Drug & Cosmetic Division
Regional Councilor Presentation

ASQ
The Global Voice of Quality™

ASQ Involvement

- As one of the largest Quality Organization in the world, ASQ Food Drug and Cosmetic Division takes the initiative of the WHO and BARQA to develop a national quality standard for biomedical laboratory research in the US which could later on lead to an international ISO standard

WHO – World Health Organization
BARQA – British Association of Research Quality Assurance

Description of project

- To develop a standard detailing formal Quality requirements for work performed during exploratory (non-GLP and non-GCP) science.
  - This work serves as a basis for drug development.
- Establishing guidance documents to ensure the integrity and validity of the scientific data generated with respect to studies and experiments.

What is a Standard/How is one developed?

- Defined - Universally or widely accepted, agreed upon, or established means of determining what something should be.
- Standards have input from regulators, regulated and consumers.
  - Without review and comments by these groups, the document is only a guideline.

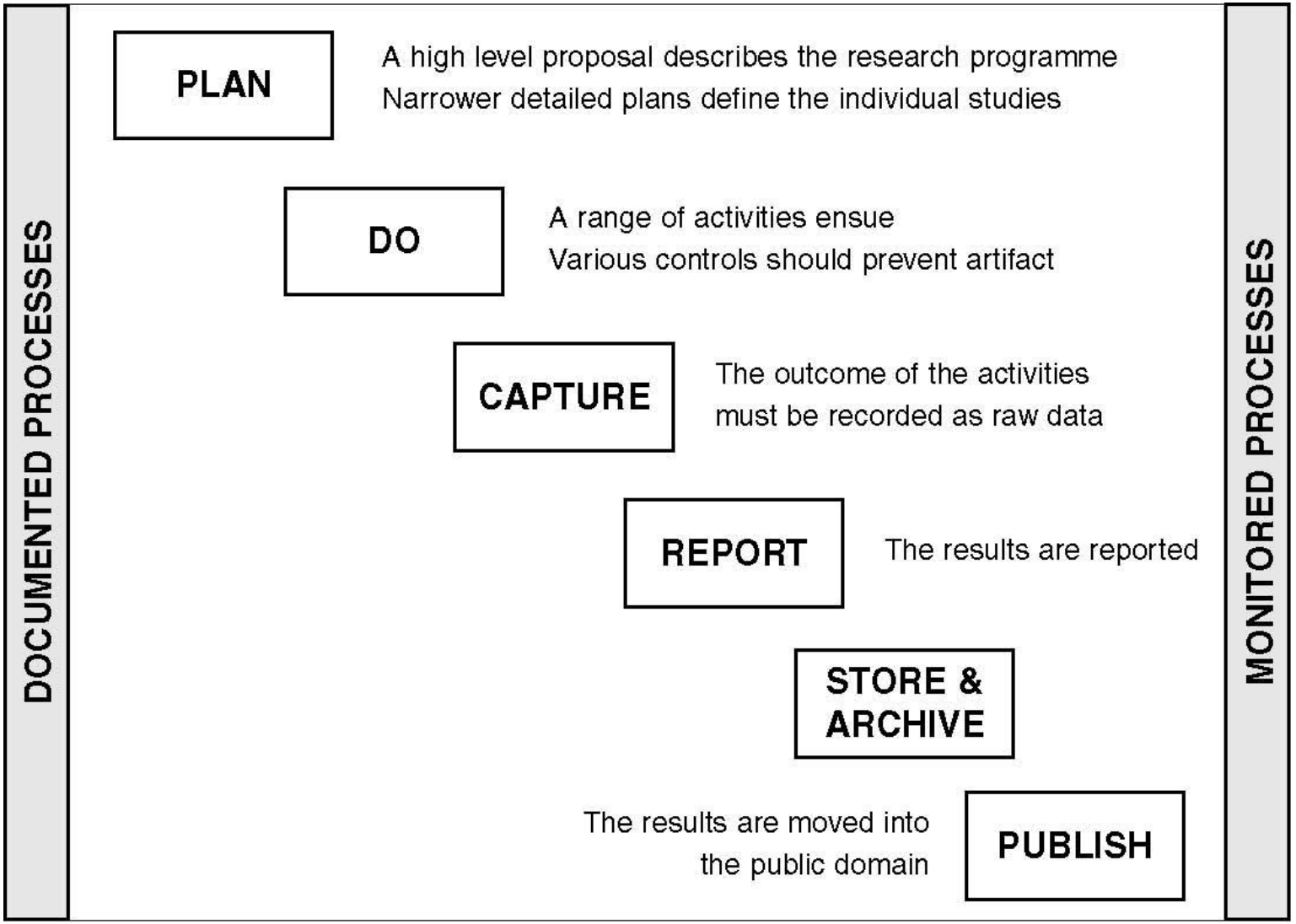
What is Biomedical Research?

- “Basic biomedical research refers to the use of fundamental scientific principles in medical and biological research directed towards developing tools to detect, prevent or treat human disease.
- Basic biomedical research is commonly encountered in the discovery and exploratory stages of product/drug development.”

WHO Handbook of Quality Practices in basic biomedical research

The flow of research activities

From Planning to Publishing



WHO Handbook of Quality Practices in basic biomedical research

Why is a Standard needed?

- No well defined quality standard exists for biomedical research in the United States
- In pharmaceutical R&D only the non-clinical (not involving humans) laboratory safety studies are governed by the GLP regulations (21 CFR 58).

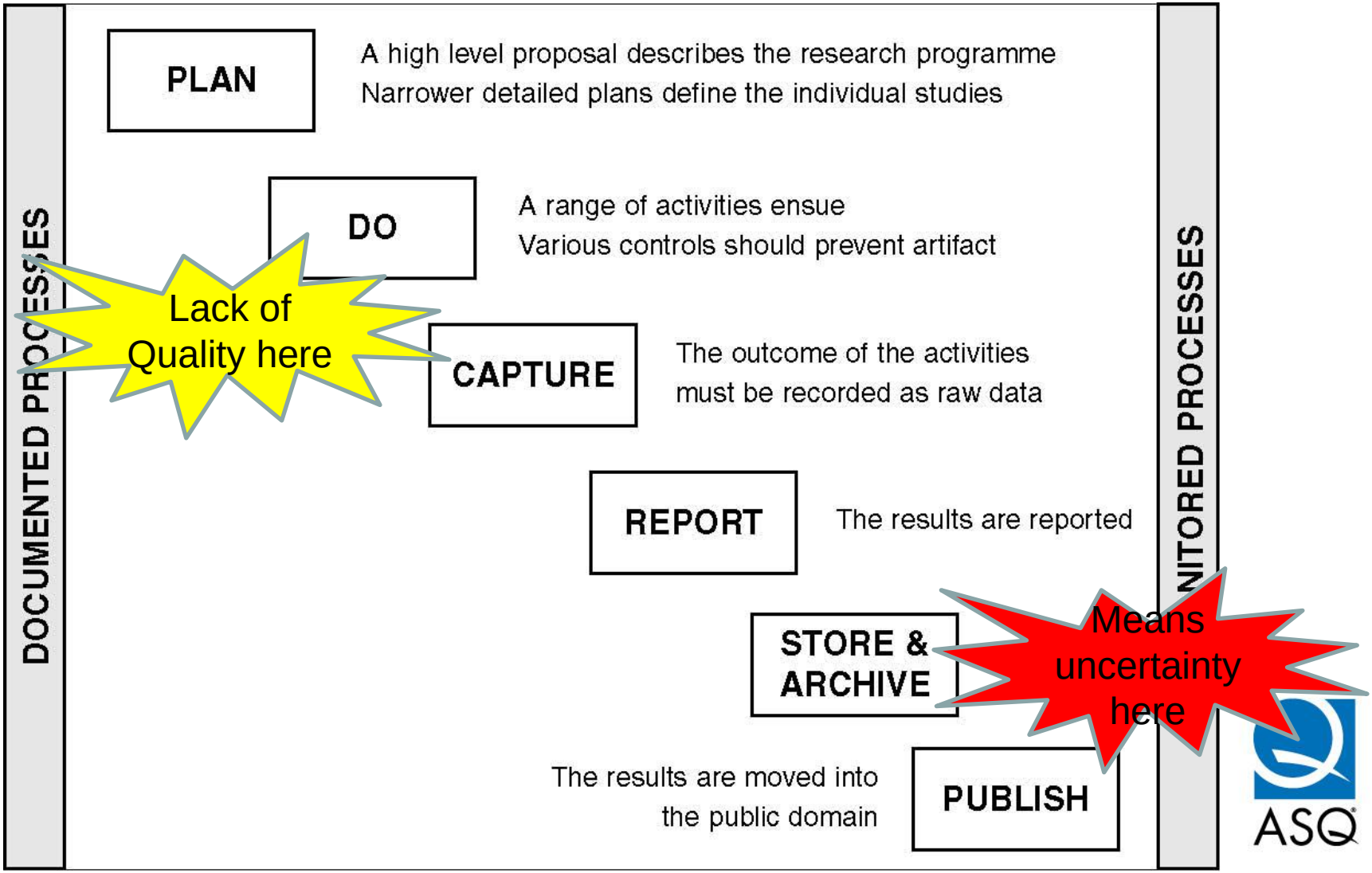
ASQ FD&C Quality Standard for Biomedical Research in Drug Development (QSBRDD)

What will the standard provide?

- Reliability and consistency of biomedical research
- Improved credibility of research across institutions
- Integration of quality science into biomedical research
- Minimized waste of resources and reduced need for costly confirmation and repetition of work already performed

Lack of Quality in research leads to unreliable results

From Planning to Publishing



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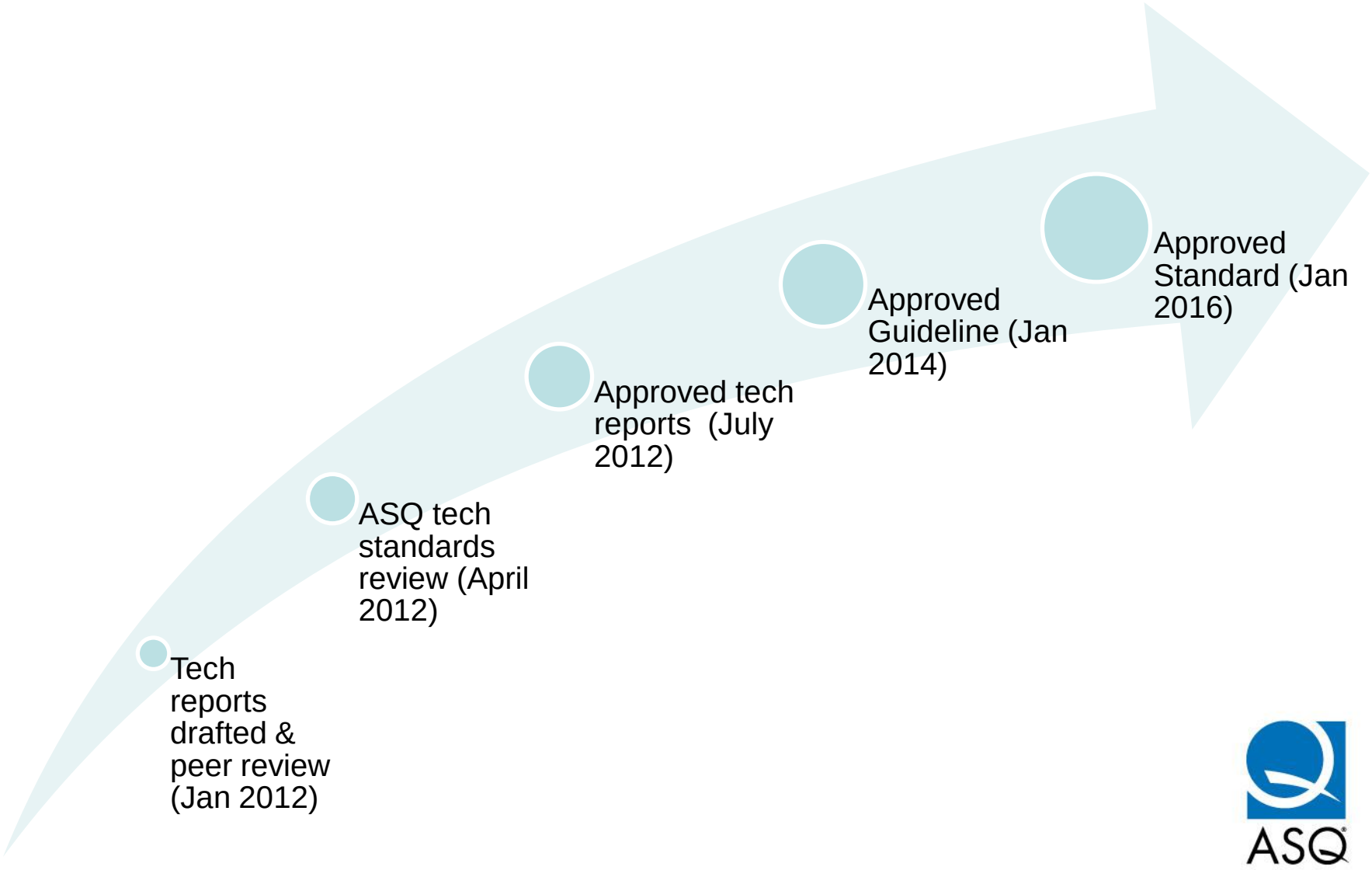
Steps of the Process & Timelines



Technical Report Content Defined

1. Scope
2. Normative References
3. Terms and Definitions
4. Management Requirements
   - e.g. Organization, quality policy, documentation, CAPA
5. Technical Requirements
   - e.g. facilities and equipment, data analysis and results reporting

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