Genentech 50th Anniversary

Innovation and ~~Influencing~~ Convincing Implementation

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CE Pharm September 28, 2026

50 Genentech
A Member of the Roche Group

WE ARE THE CHANGEMAKERS,
THE ORIGINAL RISK-TAKERS,
WITH A FOUNDATION OF FORGING
LIFE-ALTERING SCIENTIFIC BREAKTHROUGHS.
BUT OUR QUEST HAS EVOLVED
—IT'S BIGGER AND BOLDER.
OUR FOCUS IS EVEN GREATER THAN MEDICINE,
IT'S ALSO ABOUT SERVING SOCIETY.
TO SOLVE THE WORLD'S MOST
COMPLEX HEALTH CHALLENGES,
WE WILL NEED COURAGE AND ADAPTABILITY.
WE WILL CULTIVATE AND UNIFY THE GREATEST MINDS,
WITHIN AND BEYOND OUR DIVERSE NETWORK,
TO IMPROVE THE LIVES OF ALL PATIENTS.

The Genentech Promise

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The Genentech Promise

Who does the innovating?
What do we innovate?
When do we innovate?
Where do we innovate?
Why do we innovate?
How do we innovate?

Focused on Analytics

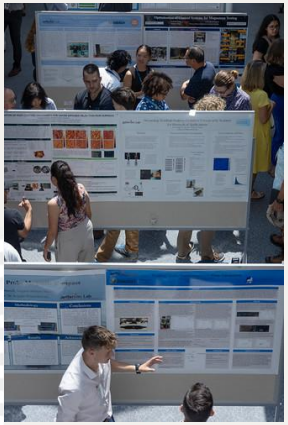


Who does the innovating?



Each of us – All of us



















What do we innovate?



Innovations in Technology



icIEF Fractionation
(R&D systems equipment)



Broadening the possibilities
(Sciex system example)



Continual evolution
of CE-MS coupling
(Agilent system example)

Methods, Method Validation/Transfer, Control Strategies/Systems, Health Authority Submissions

Methods to complement the Innovative Technologies
Methods to support novel modalities
Methods to allow alternative equipment, reagents, etc.

Development and Validation strategies to allow greater flexibility

Control systems and overall strategies to allow greater flexibility and focus on what's important for patients

Submissions to Health Authorities to allow greater flexibility, to speed time to implementation, to streamline lifecycle management



Where do we innovate?

See “Who”



When do we innovate?



All the time.

Also – see “Why”



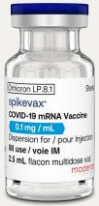
Why do we innovate?



The Molecules/Products We Develop

Novel modalities — and everything old is new again

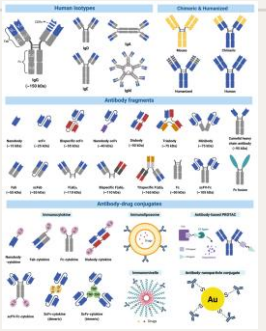
Vaccines – mRNA structural integrity



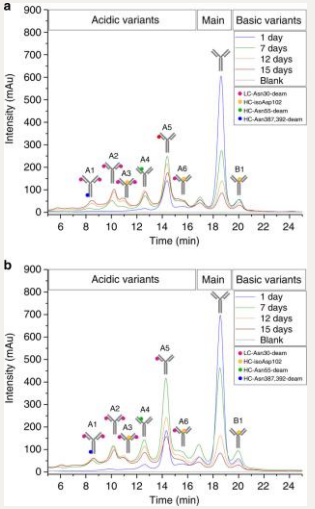
Bispecific antibodies – multi-attribute characterization of intact molecules and mismatch

ADC and PXC (protein-X conjugates) – DAR/XPR

Oligos and peptides



What are Monoclonal Antibodies?
Wang, Y. Rapid Novor Aug. 2021

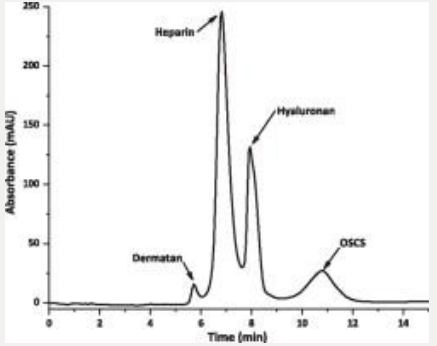


Assessment of susceptible chemical modification sites of trastuzumab and endogenous human immunoglobulins at physiological conditions. Grunert, I. et al. Communications Biology. April 2018.

Because We Have To – Patient Safety!

Contaminated Heparin –

- Detection of oversulfated chondroitin sulfate using CE (and other methods)
- Michel Girard, Health Canada



Capillary electrophoresis of heparin and other glycosaminoglycans using a polyamine running electrolyte. Loegel, T. et al., Analytica Chimica Acta. 13 Nov 2012.

- Rapid response to allow removal of contaminated lots of critical product from the market
- International harmonization of methods and standards

Counterfeit products

New variants – less well understood = greater potential for inclusion on control system (= specs)

Because We Have To – Direct and Indirect Needs

Changes in what vendors support, critical reagent shortages

- Change to a piece of equipment or software
- Addition of an alternative labeling reagent

Innovation within innovation: Multiproduct Resin Reuse and the need for sensitive detection of protein fragment (carryover)

- “We had a CZE method, but…”

GMP Compliance

- Appropriate peak integration



Support From and For Other Innovations

AI and machine learning; Robotics

RTRT and PAT

- How far can we go??



How do we innovate?



Isn’t this why we’re all here?

(This goes hand-in-hand with the Who.)



Collaboration!

The many round-robin/interlaboratory studies initiated (instigated? ;-)) by members of this community

Collaborative work on peak integration (Improvement of Peak Integration in Capillary Electrophoresis: Reference Data Set No. 1, Krompholz, M., et al., Electrophoresis. 47:276. 2026)

- Support GMP compliance, support use of AI

Across all the “who’s”:

- Collaboration between scientists and engineers (and don’t forget about Regulatory!)
- Collaboration between development and QC labs
- Academia, vendors, pharma truly listening to each other
- Pharma and Health Authorities



Blood, Sweat, and Tears (?!)

For major innovations, most likely, what's needed first is approval from management/ governance boards to use resources.

Determine the specific issue or opportunity.
Identify and recruit the right people to tackle it.

Perform meticulous and comprehensive design development and lab work.

- Fully engineered development plans.
- Carefully designed and controlled studies and model units. Might ultimately include method validation/transfer/equivalency studies.
- Unbiased assessments of results.
- Critical Thinking.

Draw clear conclusions.



Implementation and Flexibility

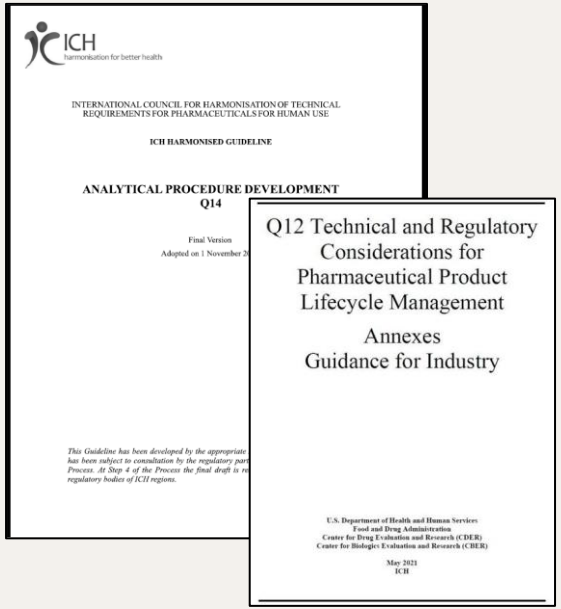
Internal implementation:
Finalized, signed-off reports for validation/IQ, OQ, PQ/etc., Governance boards (which can also need convincing), SOPs and other GMP documentation

For regulated industry:
Changes/innovation frequently require submission and approval
New or revised dossier sections- analytical examples:

- S.2.2/P.3.3, S.2.4/P.3.4, S.2.5/P.2.6/P.3.5 (re RTRT/PAT)
- S.3.1 (re novel methods for characterization, maybe S.2.5/P.2.3 if used for process development)
- S.4.1/P.5.1, S.4.2/P.5.2, S.4.3/P.5.3, S.4.5/P.5.6, S.7.2/P.8.2

Updated Regulatory Strategies, e.g., Q12/14

- Concepts aligned with previous QbD for analytics/ Target Analytical Profile discussions



Health Authority Interactions and Submissions

Specific programs for (major) innovation – U.S. FDA ETP/CATT Emerging Technology Program/CBER Advanced Technologies Team), EMA ITF (Innovation Task Force)

Standard meetings/Scientific advice

Regulatory perspective:
Regulators do support innovation, but they need to be cautious.
They have a duty to the public to ensure safe and effective drugs- they must get it right.
(Plus, there are thousands of meetings and submissions a year.)

Therefore, regulators tend to have a low tolerance for poorly presented information, lack of clarity, lack of critical thinking, incorrect information, missing information, unsupported conclusions and proposals, “influencing”…



Influencing

Swann: “Blackmail me?”

Tony: “Influence you”

Dial M for Murder



What FDA thinks of “influencing” - a few quotes from my former colleagues:

“It means affecting the outcome of something else.”

“Convincing seems a better term.”

“Regulators are compelled by data driven arguments. Never influenced.”

“Influencing is not what you want to do.”

“Hopefully you are the influencer and not the influencee.”

“Influence has a connotation of manipulation.”

“It actually sounds like you’re doing something illegal.”



Storytelling- The Art that goes with the Science

Know your audience – Are you trying to convince management/governance?
Are you trying to convince Health Authorities?

- Understand the context and situation.
- What is their reference point?
- What matters to them?

Know your purpose.

Keep it simple (when you can). Stay on point.

Be logical and clear.

- Stories don't always need to be told in chronological order.

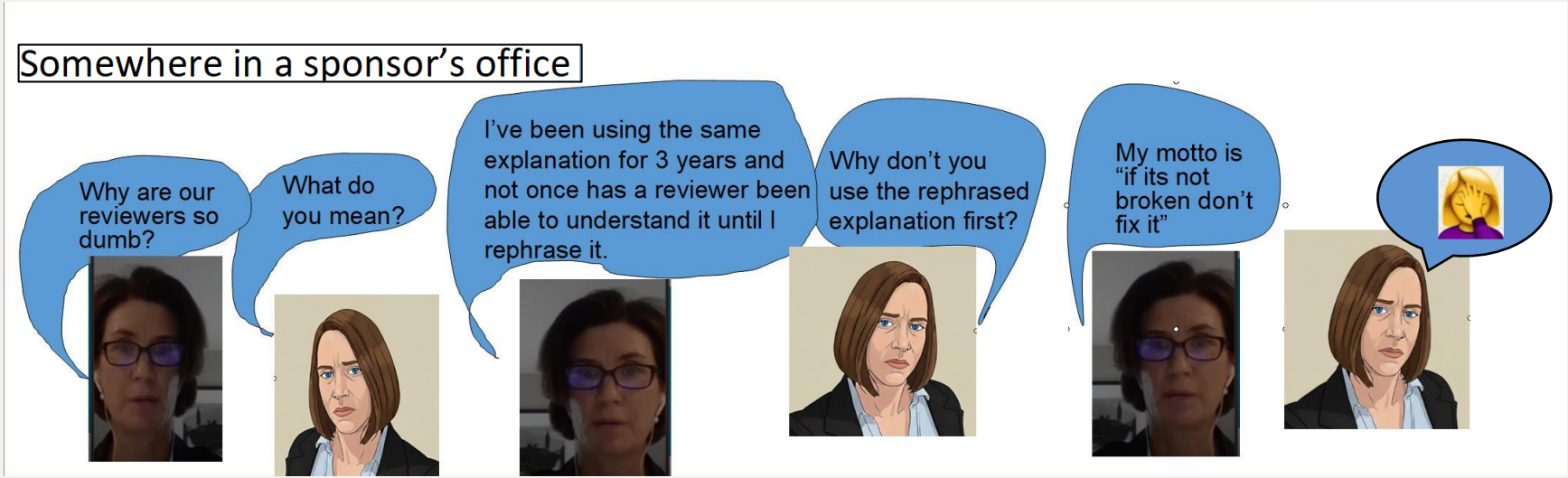
Be complete.

- This does not necessarily mean comprehensive- but provide sufficient data/information to support.
- What do they need to know?

Ensure correctness.



Clear and Correct Communication



"Repeating Mistakes and Poor Communication"

From: Pet Peeves and Roadblocks in CMC: Improving your Quality Submissions through the Product Lifecycle – The 2026 Version. Marjorie Shapiro and Chana Fuchs (Retired CDER/FDA). WCBP 2026.

“What we tried to do in the early days of Genentech was to create a culture where anything was possible.”

Bob Swanson | Genentech Co-founder