Autumn Focus Workshop
Managing GCP in Regulated Bioanalysis

Setting the Scene

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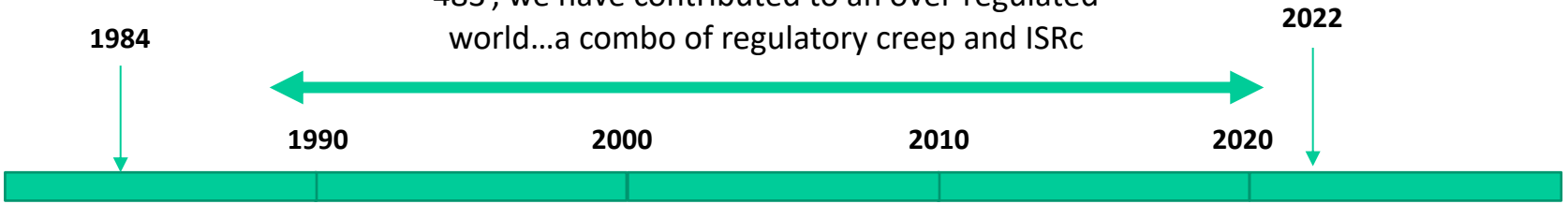
The era where we started to ‘regulate ourselves’ and defined criteria that made sense to us without realising they would become guidelines

Time to take responsibility for our next generation of scientists and take out the fear factor, having the patient on our radar

Driven by internal and external factors or ‘fear for 483’, we have contributed to an over-regulated world…a combo of regulatory creep and ISRc



Challenging
and defending science
was appreciated by mgmt and the regulators

Challenging and defending science is still appreciated by the regulators, albeit not by all, and certainly not by mgmt.

Always good to know where things come from

Origin of GxP – nuances taken out

GLP

Prevent fraud

GCP

Prevent ineffective clinical trials and protect the integrity of the patient

GMP

Prevent people getting killed and protect the customer

Origin of GxP – nuances taken out

GLP

A quality system of management controls for research labs to ensure the uniformity, reliability, consistency, reproducibility, quality and integrity of products in development for human or animal health (including pharmaceuticals) through non-clinical safety tests; from physio-chemical properties through acute to chronic toxicity tests.

GCP

An international quality standard, which governments can then transpose into regulations for clinical trials involving human subjects.

GCP follows the ICH, and enforces tight guidelines on ethical aspects of clinical research.

GCP aims to ensure that the studies are scientifically authentic and that the clinical properties of the investigational product are properly documented.

GMP

Guidelines providing minimum requirements that a manufacturer must meet to assure that their products are consistently high in quality, from batch to batch, for their intended use.

GMP resulted from a long history of the need for consumer protection since the “1903 Poison Squad” and Upton Sinclair’s ”The Jungle, 1905”

GxP

GLP

1. Organisation and Personnel
2. Quality assurance program
3. Facilities
4. Equipment, reagents and materials
5. Test systems
6. Test and reference items
7. Standard operating procedures
8. Performance of study
9. Reporting of results
10. Archival - Storage of Records and Reports

GCP

1. Ethical considerations - Helsinki
2. Trial risk *vs* trial benefit
3. Integrity and safety of trial participants
4. Information on the Medicinal Product
5. Good quality trial described in a clear protocol
6. Compliance with the study protocol
7. Medical decisions
8. Treained and experienced trial staff
9. Informed consent
10. Accurate recording, interpretation and handling of trial data
11. Confidentiality protecting trail participant
12. Good Manufacturing Practice
13. Quality assurance program

GMP

1. Quality management
2. Sanitation and hygiene
3. Building and facilities
4. Equipment
5. Raw materials
6. Personnel
7. Validation and qualification
8. Complaints
9. Documentation and recordkeeping
10. Inspections & quality audits

Scope of GxP – diving deeper

GLP

OECD 1
OECD 2-22
21 CFR 58
21 CFR 11
WHO Handbook of GLP

For BA: Clear inspection expections, at least in OECD

Guideline enforcement sensitive to individual inspector(s)/(ate) interpretations

GCP

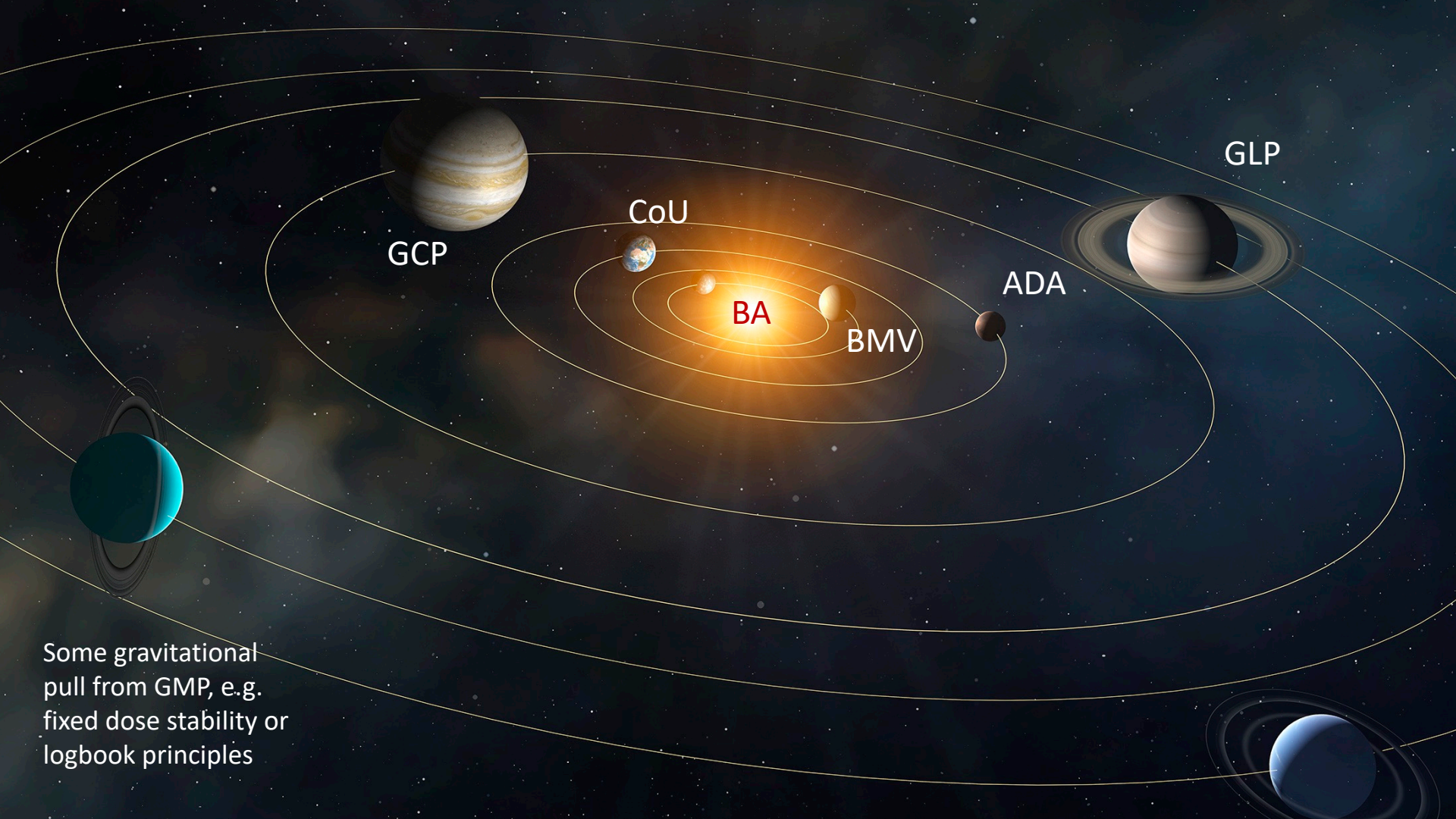
ICH E6 (R2)
WHO Handbook of GLP
EMA
EMA 2005/28/EC Clinical trial directive
Etc…

For BA: clear inspection expectatoins, at least in MHRA,

Guideline enforcement seems to be fluid and

GMP

Start with “21 CFR Part 314, 210, 211, 212, 600 and likely many more in subchapters in title 21 of CFR” or “EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guideline”


GCP
CoU
BA
BMV
ADA
GLP
Some gravitational pull from GMP, e.g. fixed dose stability or logbook principles

GCP = GLP

What is the same ?

What is different ?

They are identical twins

Pictures removed

Really?

Pictures removed

We try to identify the differences but take it too far

Pictures removed

We try to identify at the similarities and believe there are lot

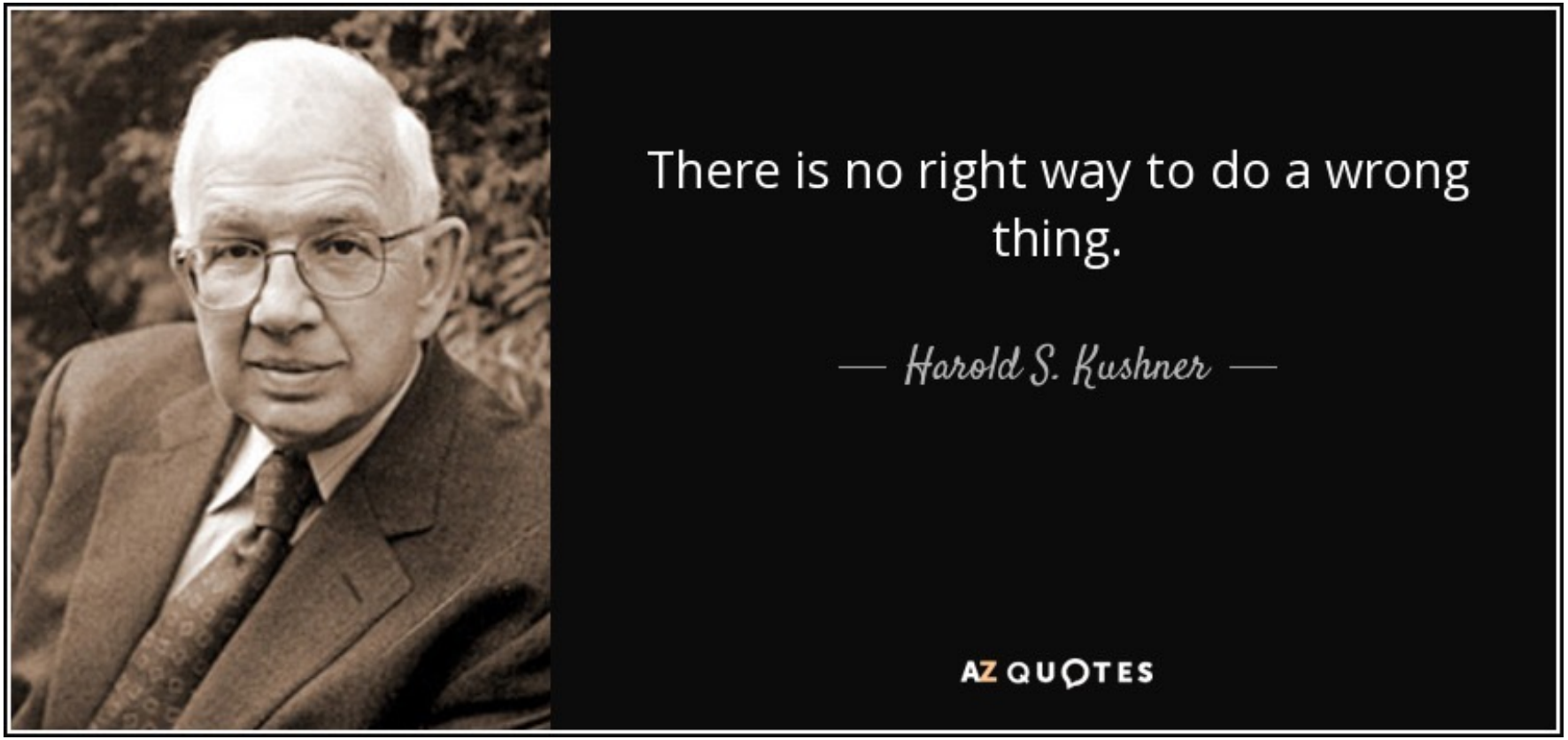
Pictures removed

But are we critical?

Pictures removed

=

our task for this workshop


There is no right way to do a wrong thing.
— Harold S. Kushner —
AZ QUOTES

There is only 1 discipline where raising the bar makes sense…