Integrity – Trust is the Crux

Preview

A. FDA and Integrity (Brief History)

B. Conditions for Integrity Failures with Real Experiences

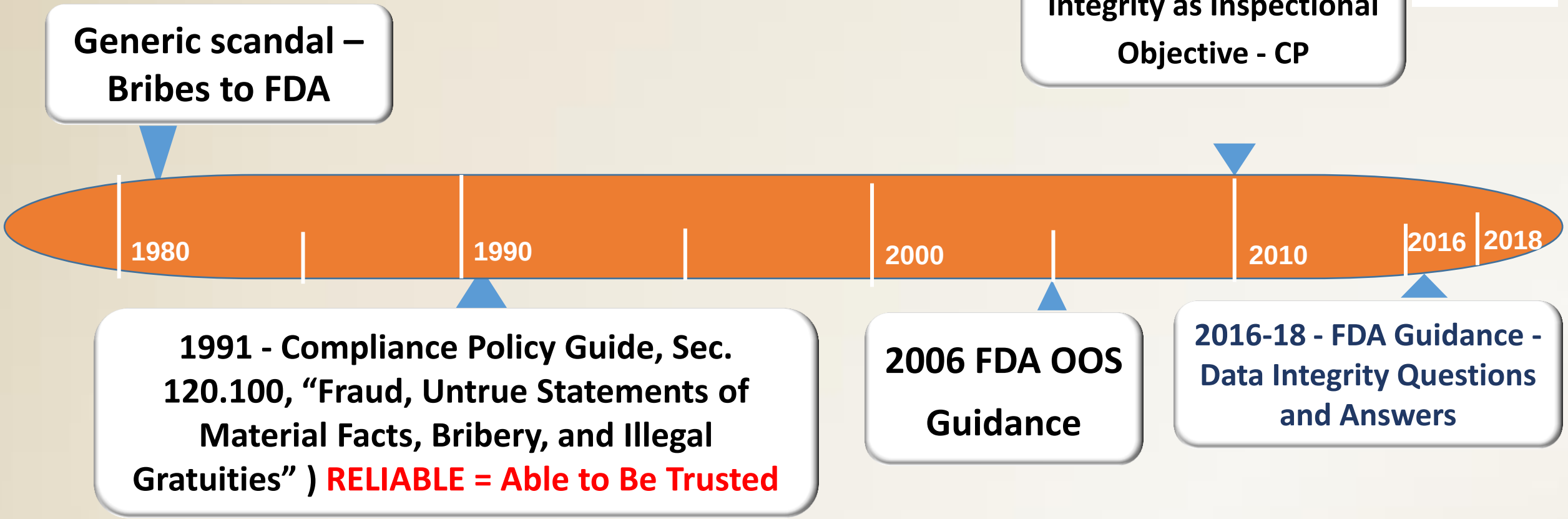
C. Why is Integrity Important?

D. Do's and Don'ts

E. Conclusion

Background on FDA and Integrity

Background on FDA/Integrity



* 2015: MHRA GMP Data Integrity Definitions and Guidance for Industry
* WHO Expert Committee on Specifications for Pharmaceutical Preparations and others
* Available on the Web

Conditions under which Integrity Failures Can Happen

Why do Integrity Issues happen?

Conditions

Motive/Incentive

Rationalization

Opportunity/Lack of Controls

\+ **(or a combination of such)**

= **Data Integrity Breach**

Conditions: Experiences

Incentive / Motivation - Examples

- First to File
- Financial or Other Gain
- Told To Do It (can't challenge boss)
- Shortcuts → Increased Production
- Cover Errors (embarrassment)
- External pressure (Customer? Sales?)

The Best Security
Top Down
AIP

Conditions: Experiences

Perfect Records
What FDA wants?

Rationalization – Examples:

- Audited by FDA and they never check this
- My boss/QA trusts me
- Ignorance/Cultural-Perfection/Bad Habits
- Peer pressure – benefits company
- Everyone else is doing it
- Easier this way /Leave on time (take shortcut)

Conditions: Experiences

Trusted Production Manager - Girlfriend

Opportunity - Examples

- Night shift / Working alone
- Ineffective QA (balance of power?)
- No one is checking or checking is infrequent

Conditions: Experiences

Lack of Controls - Examples

- Old equipment/Manual Processes
- No audit trails
- Buddy
- No one verifying
- Routine
- Procedures: unavailable/unclear/bad/not followed

Friends
Making own decisions

Why is Integrity Important?

“The Moment there is suspicion about a person’s motives, everything he does becomes tainted.”

Mahatma Gandhi (Quote)

Trust

Doubt

Doubt

Excerpt from FDA Warning Letter

"This data falsification and the record-keeping deficiencies described above **raise doubt** regarding the validity of your firm's records."

Do's & Don'ts

Do's and Don'ts – DOs

- Have a Data integrity policy with **defined consequences**
- Getting together to determine possible data integrity breaches the facility or the conditions mentioned
- Transparency – Open Deviations/Investigations
- Spot checks, show me, tell me
- Review audit trails
- Have an anonymous box for reporting Integrity issues
- Train in data integrity – make part of annual training? Weekly or Monthly reminders part of Company policy?

Do's and Don'ts – DON'Ts

- Do not deny access to facilities and records FDA is entitled to
- Do not tolerate authoritarian managers - do it my way or the highway
- Do not oppress employees
- Do not pre-sign records before completing operations
- Do not hide mistakes
- Do not backdate
- Do not re-write
- Do not transcribe data

"ALCOA"

- Do not write on scrap paper or unauthorized notepads
- Do not tear up paper or destroy records

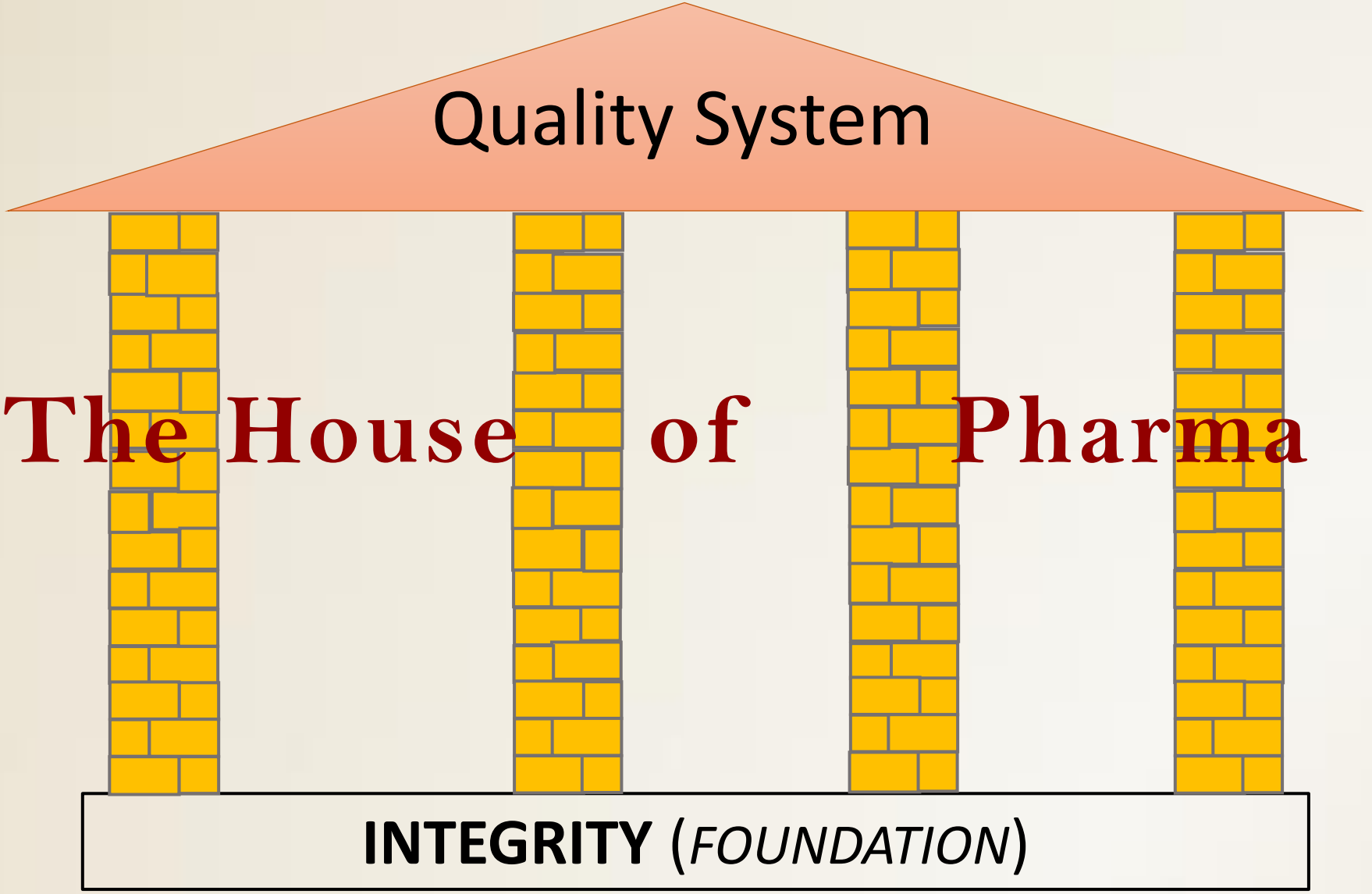
In Conclusion

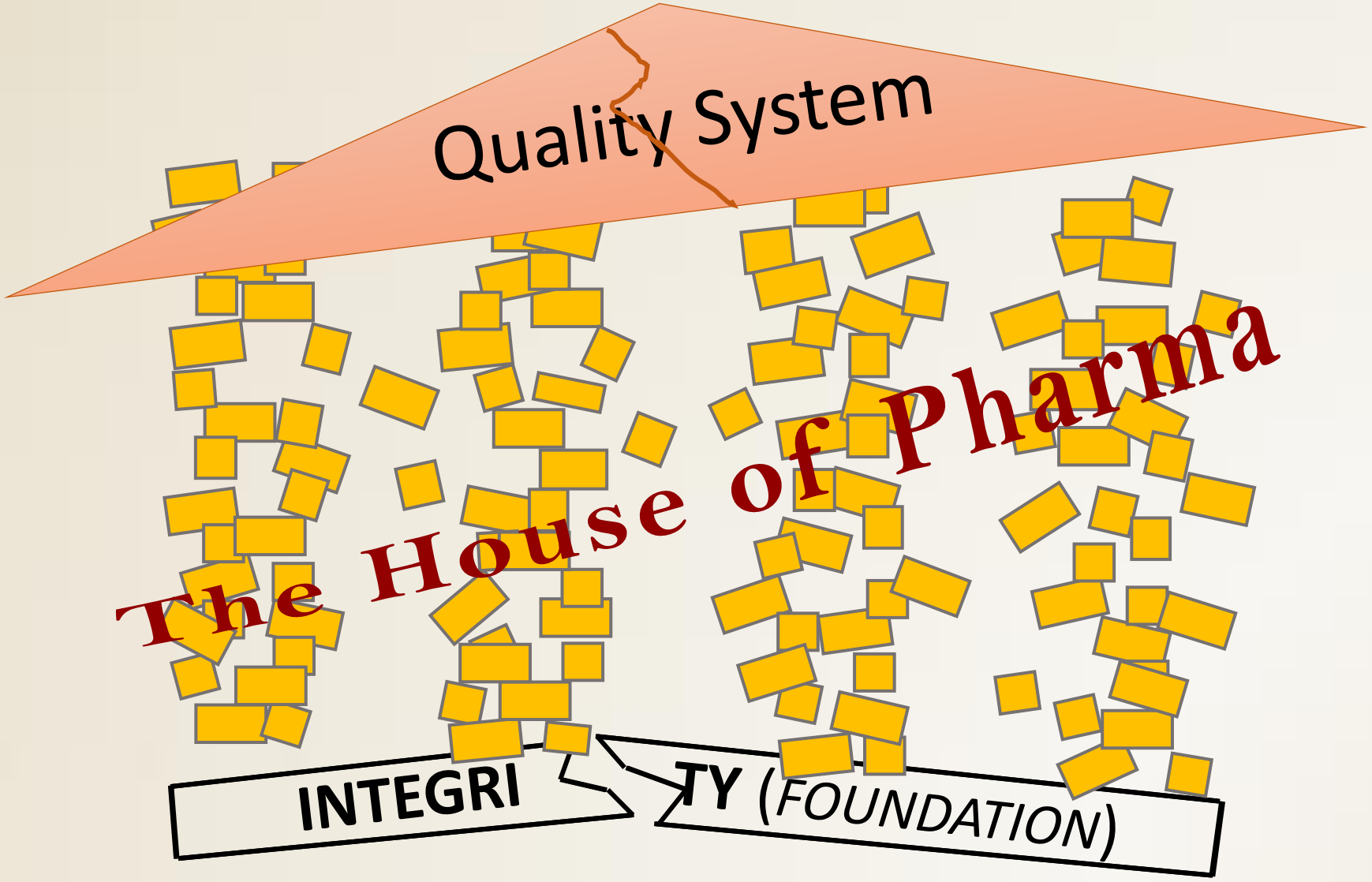
Integrity means:

What you are
Doing, Recording and Saying
is REAL.

Common Sense – Data Integrity

- Perform activities as if your customer / FDA is watching
- Follow ALCOA +
- Transparency


Quality System
The House of Pharma
INTEGRITY (FOUNDATION)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धन्यवाद

Thank you!

GRACIAS!

THE END!