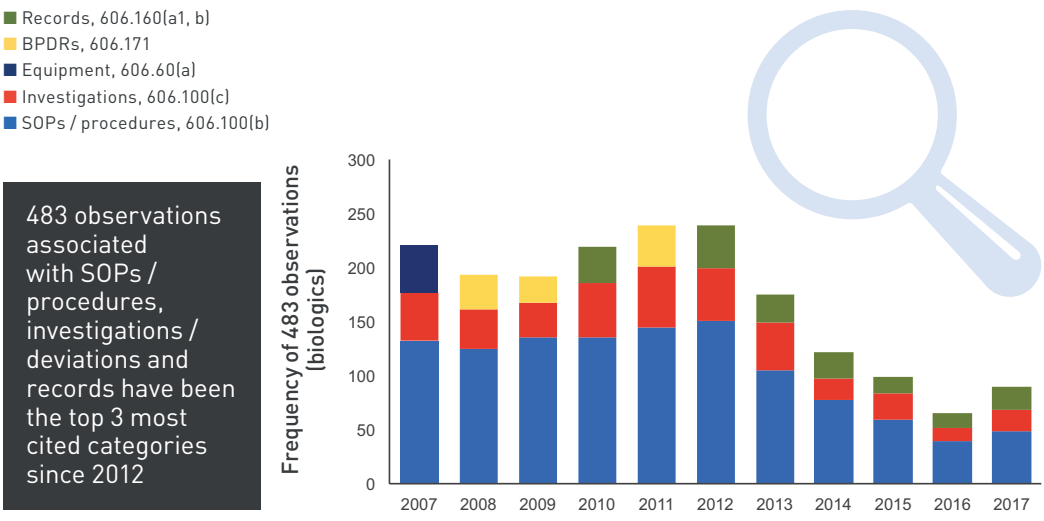
PAREXEL®
YOUR JOURNEY. OUR MISSION.®

GMP COMPLIANCE IN BIOLOGICS — IMPROVEMENT NEEDED

1 FDA Inspectional Observations (Biologics), 2007-2017 Top 3 cited FDA Form 483 observations

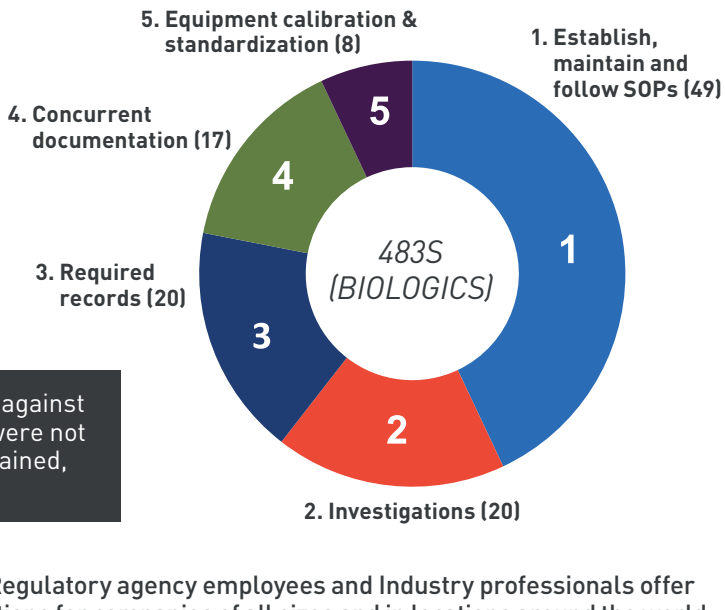


483 observations associated with SOPs / procedures, investigations / deviations and records have been the top 3 most cited categories since 2012

Source data: https://www.fda.gov/ICECI/Inspections/ucm250720.htm

2 Top 5 inspectional observations (biologics), 2017

From inspections ending between 10/1/2016 and 9/30/2017, data from FDA's electronic inspection tools

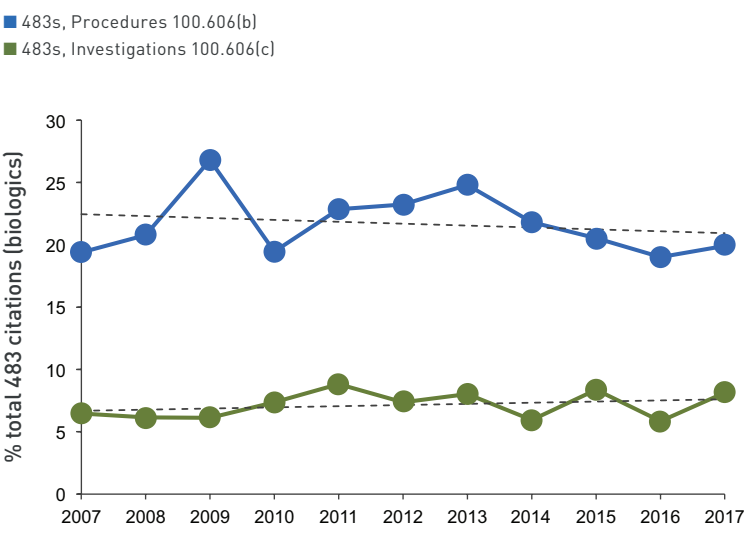


The most 483s were cited against 21 CFR 606.100(b); SOPs were not always established, maintained, followed or available

PAREXEL's team of former Regulatory agency employees and Industry professionals offer time-tested compliance solutions for companies of all sizes and in locations around the world.

Source data: https://www.fda.gov/ICECI/Inspections/ucm250720.htm

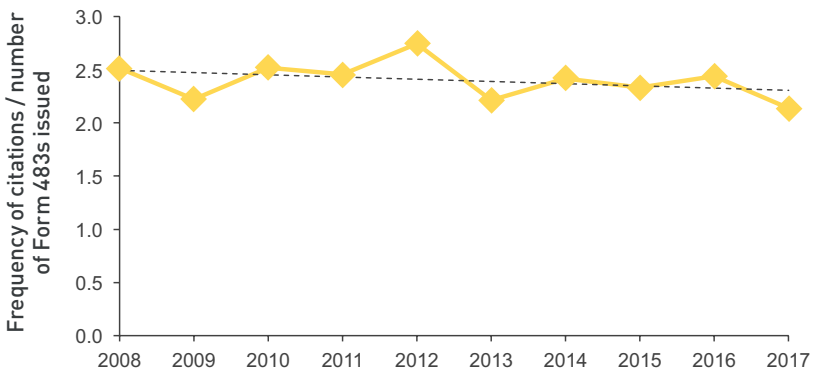
3 Procedures not maintained / followed and investigations account for 25% of 483 observations



The proportion of 483s associated with SOPs / procedures and investigations has remained relatively constant (% 483s per annum) since 2007

PAREXEL develop practical, tailored plans that align quality capabilities with business strategy

4 Number of Form 483 observations (biologics)



The average number of observations per Form 483 issued has remained relatively consistent since 2008

Source data: https://www.fda.gov/ICECI/Inspections/ucm250720.htm

PAREXEL CONSULTING

PAREXEL's team of former Regulatory agency employees and Industry professionals offer time-tested compliance solutions for companies of all sizes and in locations around the world.

We develop practical, tailored plans that align global quality capabilities with business strategy, understanding that preemptive compliance and effective crisis management are critical to a successful product journey.

To discuss how PAREXEL Consulting can assist with your regulatory, manufacturing or GMP compliance challenges please contact regulatory.portal@PAREXEL.com.

In the past 5 years, PAREXEL Consulting has assisted over 500 global-footprint clients with:

- Inspection readiness (mock inspections, training, coaching, on-site support)
- Risk Mitigation (preparation of 483 and WL remediation strategy with on-going support)
- Meetings and regulatory communiques (organizing meetings, preparation of presentations)
- Enterprise-wide Operational Excellence (Lean processes; sterile manufacture; IT systems; process validation)
- Quality Metrics (for early detection and risk prevention)
- Supplier Quality Assurance (CMOs, entire supply chain)
- Data Integrity Assurance