VALIDANT

Event Investigations

What is the true root cause of your deviation or OOS?

Confidently answer that question with Validant.

Event investigation deficiencies remain among the top 5 most frequent inspection observation citations given by the FDA today[1] – leaving companies exposed to significant liability and putting patient health at risk.

Did you know?

Validant's global network includes

3,500+ strategists, operators, and regulators.

Bring in the Experts:

Improve Investigations and Raise Your Quality Standard with Validant

Validant's team has helped hundreds of pharmaceutical and medical device clients, from start-ups to top 30 leaders, implement sustainable investigation processes that drive compliance and better science.

Whether you need additional staff to expertly handle your event backlog or a full strategy to solve large-scale, multi-site investigation system challenges, Validant will deliver the expert resources you need, when and where you need them.

Resourcing Strategies

Validant's GMP experts will integrate seamlessly into your team and bring with them the tools to perform in-depth root cause analysis (RCA), product quality impact reviews, and risk assessments, yielding corrective and preventive actions (CAPAs) that drive sustainable improvement.

[1] Pharmaceutical Online, 2019

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Consulting Strategies

While every engagement is unique, Validant works through a proven and repeatable process to reduce backlog, remediate FDA findings, and improve processes.

Event Review and Triage

To prioritize event investigations by criticality and collect comprehensive data for RCA.

Product Quality Impact and Risk Assessment

We ask the right questions to determine product quality impact and assess risks.

Root Cause Analysis

Providing the resources needed to efficiently, but thoroughly, determine root cause.

Creation of CAPA Plan & Procedure Updates

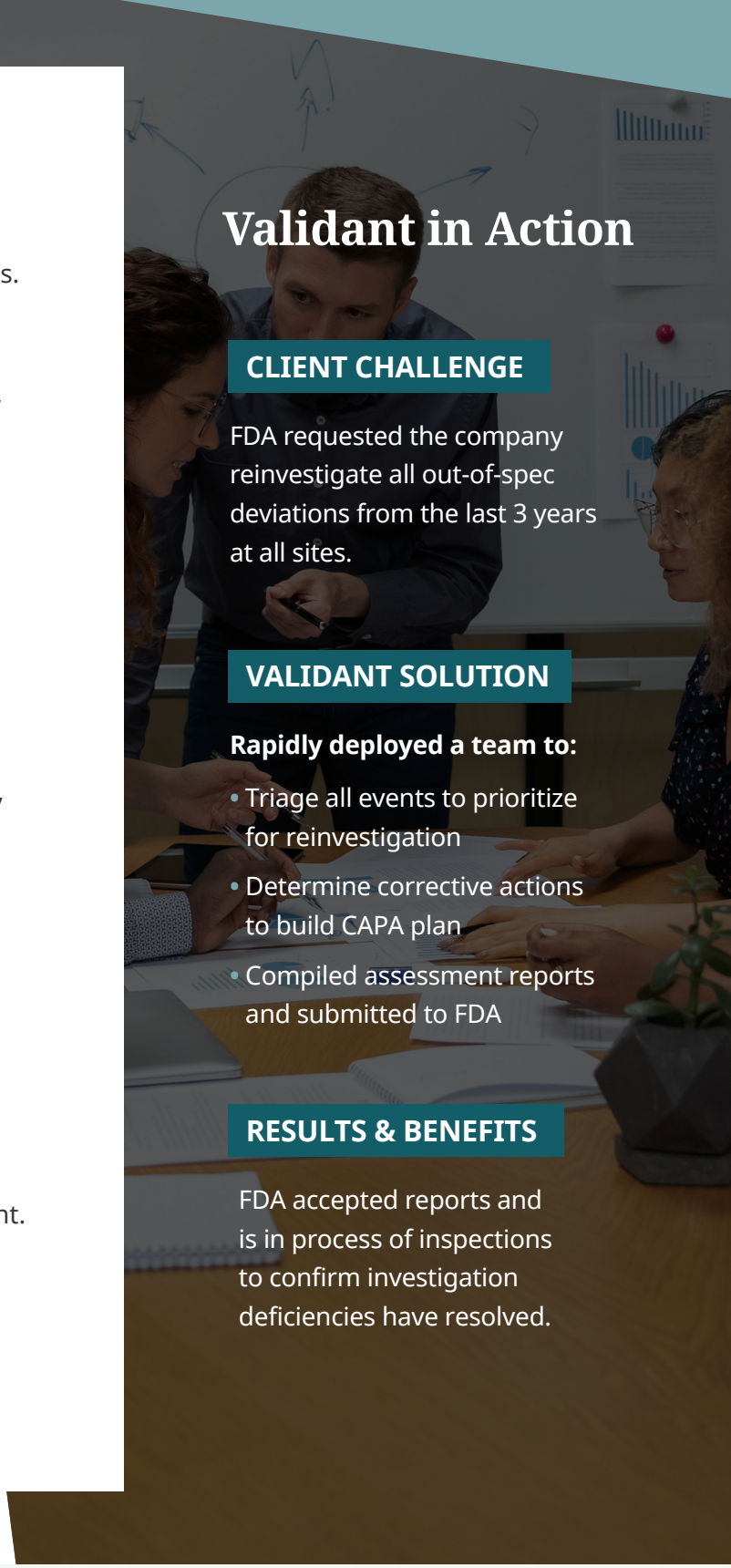
Our team can also help with implementation and documentation of CAPA completion.

Effectiveness Checks (ECs)

To verify CAPAs adequately addressed the event root cause and are driving improvement.

Team Training & Knowledge Transfer

Mentoring your internal team throughout to empower continual improvement.



Validant in Action

CLIENT CHALLENGE

FDA requested the company reinvestigate all out-of-spec deviations from the last 3 years at all sites.

VALIDANT SOLUTION

Rapidly deployed a team to:

- Triage all events to prioritize for reinvestigation
- Determine corrective actions to build CAPA plan
- Compiled assessment reports and submitted to FDA

RESULTS & BENEFITS

FDA accepted reports and is in process of inspections to confirm investigation deficiencies have resolved.

Discuss your Event Investigation needs with Validant today:

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Offices in: San Francisco, CA | Durham, NC | Boston, MA | Cork, Ireland

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