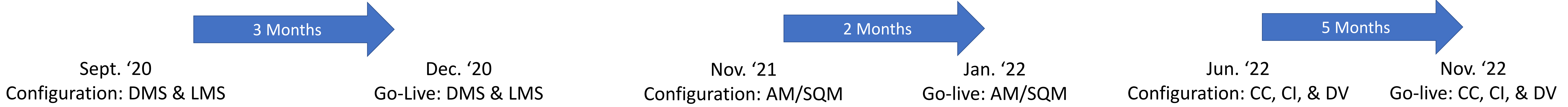


Project Timelines



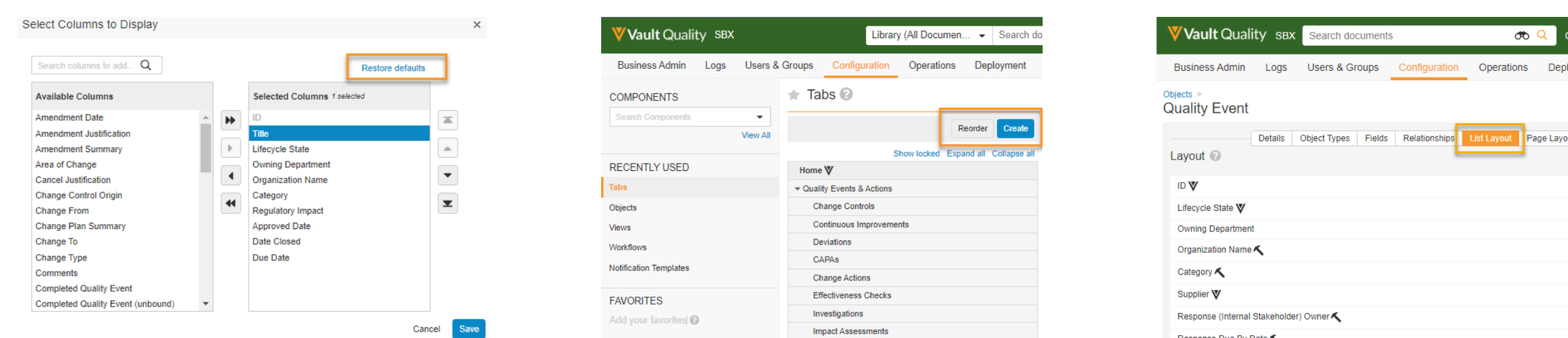
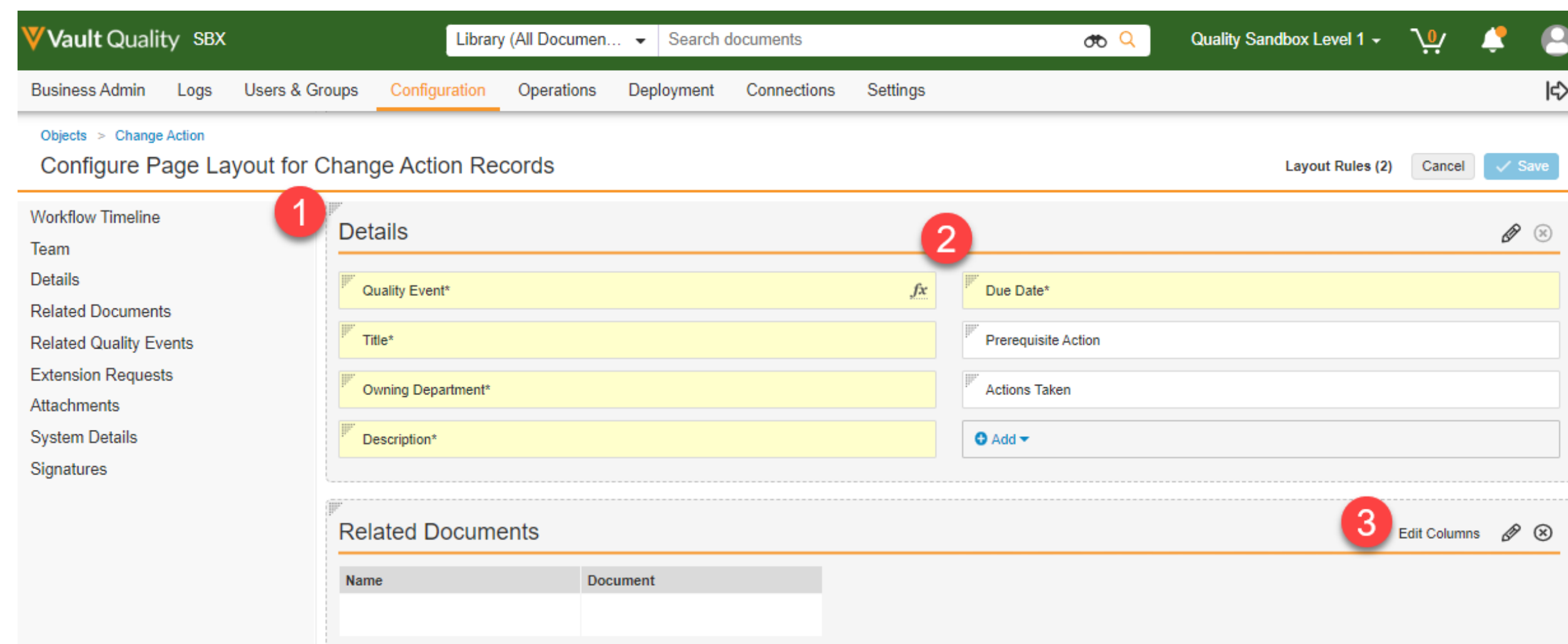
Introduction

In building Quality Management Systems, a common theme architects must keep in mind is finding solutions that are intuitive to the end user under the construct of regulations and company’s policies and procedures. A Quality by Design (QbD) system must be able to translate product functionality into end user knowledge.

How is this accomplished efficiently and with ease?

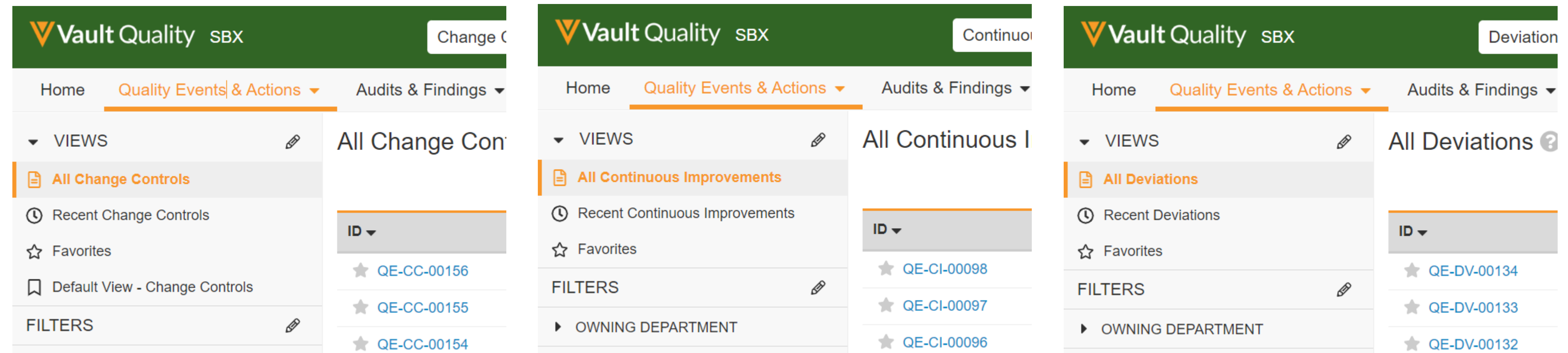
One specification includes the utilization of Quality Event Smart Numbering. Additionally, by enhancing metadata location through page layouts and column adjustments, commonly asked questions will be self-answered.

Adjusted Page Layouts



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Quality Event Smart Numbering



Quality Event Smart Numbering: Summary and Considerations

- Nomenclature changed from standard QE-123456 into QE-AB-12345.
- Decision was made to match all Quality Management System objects as 5 digits, similar to those in Document Management System.
- Embedded abbreviations are now standard across all Quality Events including non-closed records from previous implementations.
- Future implementations utilizing Quality Events must have new abbreviations.

Adjusted Page Layouts: Summary and Considerations

Numbered Steps Correspond to Figure on Left, e.g., Configuration → Objects → “Object Name” → Page Layouts

1. Ability to modify Section order.
2. Sections containing fields may be adjusted to match look and feel along different processes, e.g., Details, System Details, Signatures.
3. Adjust pertinent columns.

- Communicate with Veeva’s configuration specialist on parameters of change.
- Find common default view as changes will impact all permissioned users.
- Users may add or subtract columns based on their personalized column selections.
- Test all mapped out metadata fields on front end.
- Ability to modify tabs and list layouts.