AUDIT DATA ANALYSIS

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Edwards Lifesciences

Introduction

Audit Intelligence is an advanced analytics data model and report that provides executive-level clarity to the quality patterns and issues that are present in the audit process. The audit process is difficult to analyze due to multiple factors like a lack of industry/ product knowledge, variations in the audit process on an auditor or auditing company level, inability to predict what information an auditor will need, and a wide variety of products.

Objective

The aim of this project is to generate insight on audit data. Specifically, there are two key areas of focus:

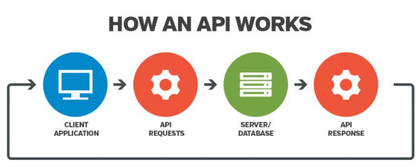
1) Utilizing audit scribe data, develop a profile on the auditor and regulatory agency. What questions are commonly asked, when, and why?
2) Utilizing external audit data, develop a profile on the prevalent issues in the industry. What issues are plaguing our competitors?

Methodology

Text data files were first grouped according to auditor and year. After this, the conversation was tokenized by speaker on a per audit basis

Questions are identified through both punctuation (ie if a '?' was present in the sentence) and the use of "question words" (ie who/what/where/when/why etc). The isolated questions were then run through a series of models including term frequency-inverse document frequency (TF-IDF) and Bag of Words (BoW). Cosine similarity was used to group the questions.

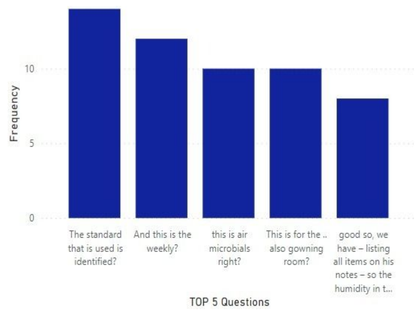
Data was extracted from MAUDE, Recall, 483 Inspection and Warning Letters databases using custom made APIs (Application Programming Interface) for both Edwards and Edwards' top competitors like Medtronic, Abbott, Livanova and Boston Scientific.



The external databases' data was then analysed using multiple NLP techniques for actionable insights.

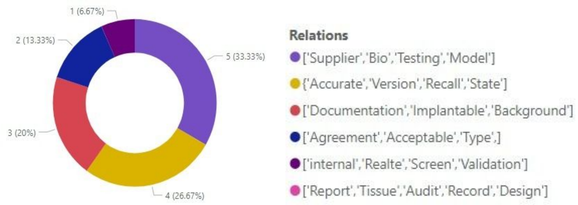
Results

Jeff's (one of the auditors) Top 5 Question Categories

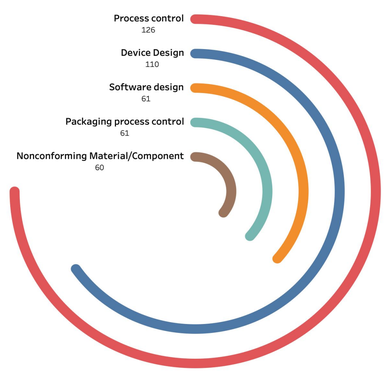


The bar chart to the left shows counts for questions grouped as similar (using cosine similarity) to the text shown on the X axis. The pie/donut chart below details the breakdown of topics spoken about during the audit process for this specific auditor.

During His Audits, Jeff Talks About…



Top 5 Root Causes for Competitors



Most Common Device Problems

Edwards	Competitors
Gradient Increase	Material Rupture
Degraded	Fluid Leak
Paravalvular Leak	Paravalvular Leak
Fluid Leak	Patient-Device Incompatibility
Calcified	Device Dislocated or Dislodged

Conclusion

Internal:

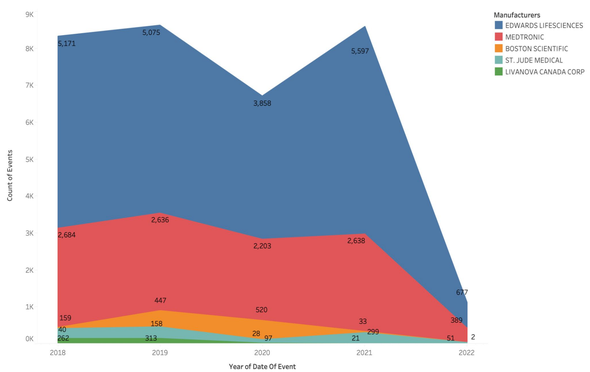
- Questions asked during the audit process typically revolve around
  1) Aspects of production like part quality, component suppliers etc
  2) Product status and
  3) Documentation/manuals related to the product

External:

- Discovered that amongst Edwards Lifesciences' competitors, Medtronic and Abbott failed to maintain proper procedures-- resulting in warning letters being issued.
- Within the medical device industry the most frequent root cause for device recalls is process control at a count of 126.
- Additionally, the most frequent device issue is Material Rupture within the competitors.
- Examined the FDA form 483 PDF files in order to analyse the quality of the products.
- Based on the inspections on competitors, we can infer that most of the problems were related to non maintenance of procedures, Design verifications and failure of device. So, Edwards could focus on avoiding such problems in their products.

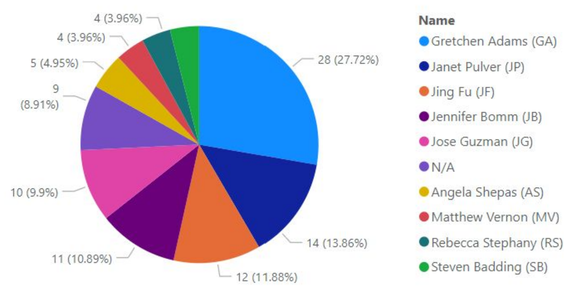
Exploratory Visualizations

Count of Device Problem from 2018 to 2022



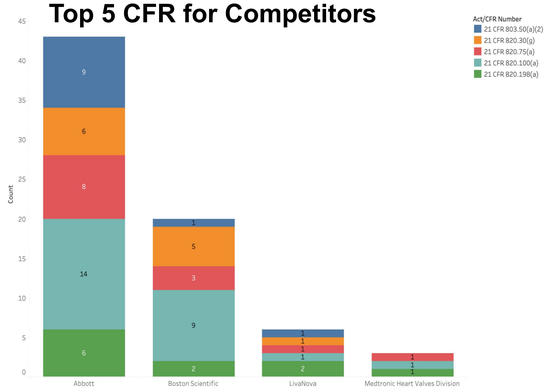
In 2020, a drop in events occurred for all main competitors, except Boston Scientific, as their product 'Lotus Edge Valve System' had more issues and recalls which lead them to bail on the product.

Count of Audit files by Auditors



Counts for audits executed are weighted towards a subset of all the auditors. Auditors GA, JP, JF AND JB comprise the majority of audit files we received. However in total there were 22 auditors represented within the data.

Top 5 CFR for Competitors



21 CFR 803.50(a)(2)- Device malfunction

21 CFR 820.30(g)- Design validation

21 CFR 820.75(a)- Lack of or inadequate process validation

21 CFR 820.100(a)- Procedures for corrective and preventive action have not been adequately established

21 CFR 820.198(a)- Lack of or inadequate complaint procedures