

Monetizing Incentives

Oct 10, 2017

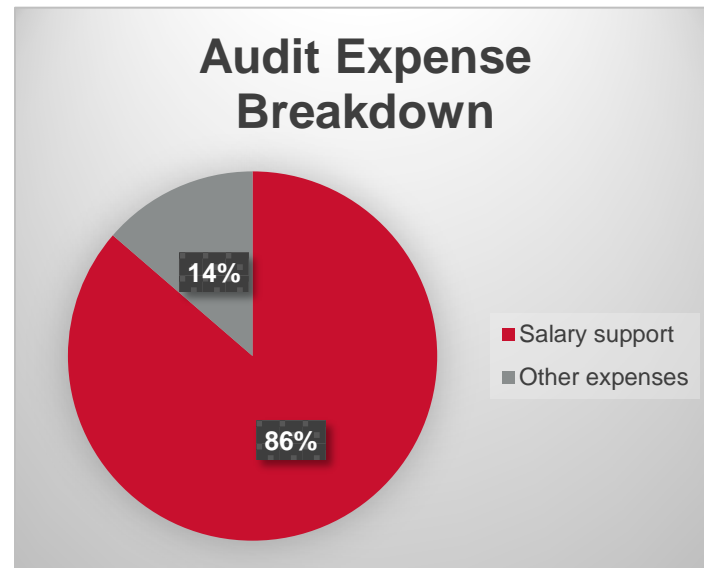
Nathan Tenzer
Rob Becker



Edwards

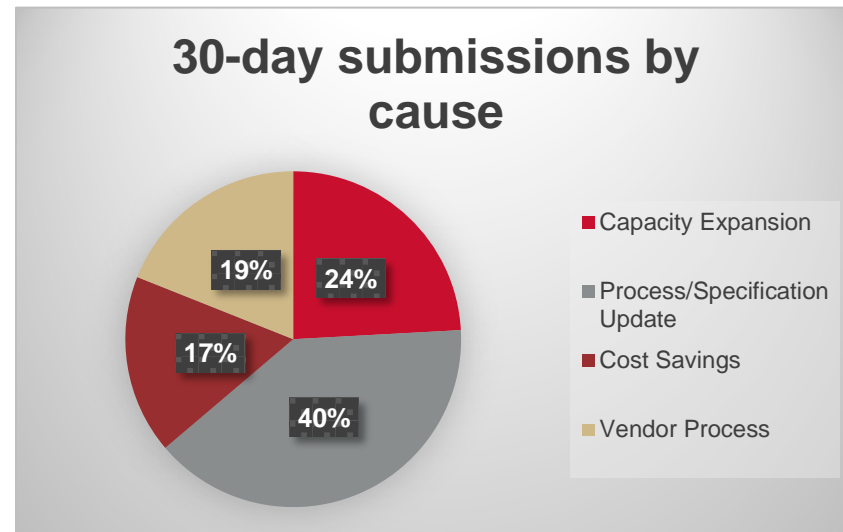
Audit support cost

- Typical audit includes:
 - Unannounced audit lasts on average 10 days
 - Audit support staff of 10 people
 - Daily rate of \$1400
- Total cost \$140K per audit
 - Conservataive estimate
 - Does not include cost of project delays, etc.



30-day submission cost

- Flagship products undergo ~60-70 submissions over product lifespan (3 yrs)
- A typical 30-day submission requires ~80 hrs to write, review, and submit
 - Total of \$480k for a single product!
- Number of submissions limited per company and reviewer agreements to ~2 submissions per month
- Severely limits ability to drive cost improvements
- \$127k in 2016 for 30-day submissions for Draper site only



Unintended consequences of 30-day submissions

- 21 CFR 814.39(f), section 515(d)
 - Interpreted (via feedback) to include modifications to a cleanroom where PMA product is manufactured
- RODI water is installed in a continuous loop to prevent stagnation
- Any change to the loop is considered a change to the environment where PMA product is manufactured

Installation complete additional loop	\$66,000
Installation additional drop	\$1,350

- Timeline to implement and approve a change:

– Installation	2 wks
– Testing	4 wks
– 30-day submission prep	2 wks
– 30-day review	4 wks
	Total 12 wks
- Based on interpretation all product manufactured in the space regardless of contact with RODI system would be on hold for 90 days
- Business decision to add an additional water loop
 - This has occurred 2 times at Draper)



Edwards

Helping Patients is Our Life's Work, and

life is now