

CHA Medication Safety Sterile Compounding Survey Report

Executive Summary

CHA surveyed approximately 148 hospitals with 208 clean rooms. Hospitals answered for each of their clean rooms undergoing or planning to undergo construction changes to meet USP Sterile Compounding requirements. The survey questions were focused on key components of the construction process and regulatory requirements to meet the December 2019 deadline.

The questionnaire was composed of 9 questions on barriers hospitals face in the three phases of the construction process: Barriers to starting construction, barriers to completing the construction and barriers to full construction completion and regulatory signoff.

Barriers to Initiation of Construction Process

While financial constraints were a major reason for construction delays, many hospitals are undecided and attempting to use alternative sterile compounding methods.

One hundred and one (101) clean rooms identified “other issues” as barriers, the “other” items included construction delays, project underway, physical space issues, construction completion, regulatory issues, undecided and not applicable. Twenty-five (25) potential clean room conversions are using alternative methods to compound for example, moving to immediate use only, using a CAI, finding an alternative location and outsourcing. Twenty-one (21) clean rooms are undecided because they are going through new ownership, are delayed in their internal capital projects and or weighing options.

Outsourcing and Vendor

Over 60 clean rooms are engaged in outsourcing activity and the highest number use CAPS as their outsourcing vendor.

Mobile Compounding Unit

Sixteen or 8% of respondents are using a mobile compounding unit.

Barriers to Construction Completion

Forty-nine (49) clean rooms are under construction while several are working through governance approval, financing, design and OSHPD sign off. Of those who answered “other”, 22% (12) are awaiting regulatory agency approval. Almost 34% (41) indicated that construction would be complete by December 1, 2019 and another 34% (41) anticipating construction completion by the end of 2020. Almost 85% who have completed construction have also received OSHPD approval. Over a third (34%) (39) of respondents anticipate having construction completed and all regulatory approvals by December 2019 deadline. Of those missing the deadline, 40% (46) expect to be complete by the end of 2020.

Most Significant Barriers to Timely Completion

Lack of funding was identified by more than 75% (128) of respondents as a significant barrier to timely completion. The inability to obtain skilled contractors and or architects was also listed by over 60% (104) as a barrier. A lack of pharmacy or staff leadership to fully inform the process change was seen as the least significant barrier to timely completion of the project (49%) (82). Over 82 respondents provided comments, of which 47 (57%) mentioned a problem with one of the regulatory agencies, Office of Statewide Planning and Development (OSHPD), Board of Pharmacy (BoP) or California Department of Public Health (CDPH) as a problem.

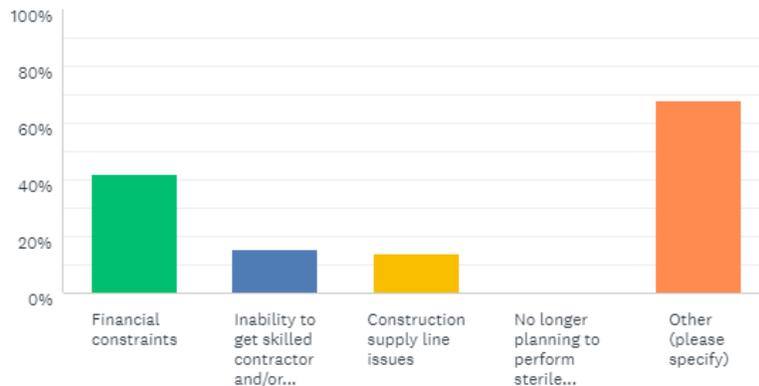
CHA Medication Safety Sterile Compounding Survey Results

Question #1 - How many pharmacy clean rooms are currently performing sterile compounding in this hospital? If more than one they will complete question for each clean room – data collected on 8/16/2019, from approximately 148 hospitals - total number of clean rooms = 208

Question #2 – if the construction process has not yet been started to meet the new standards, please identify the reasons why

Clean Room 1. If the construction process has not yet been started to meet the new standards, please identify the reasons why. (Check all that apply)

Answered: 148 Skipped: 60

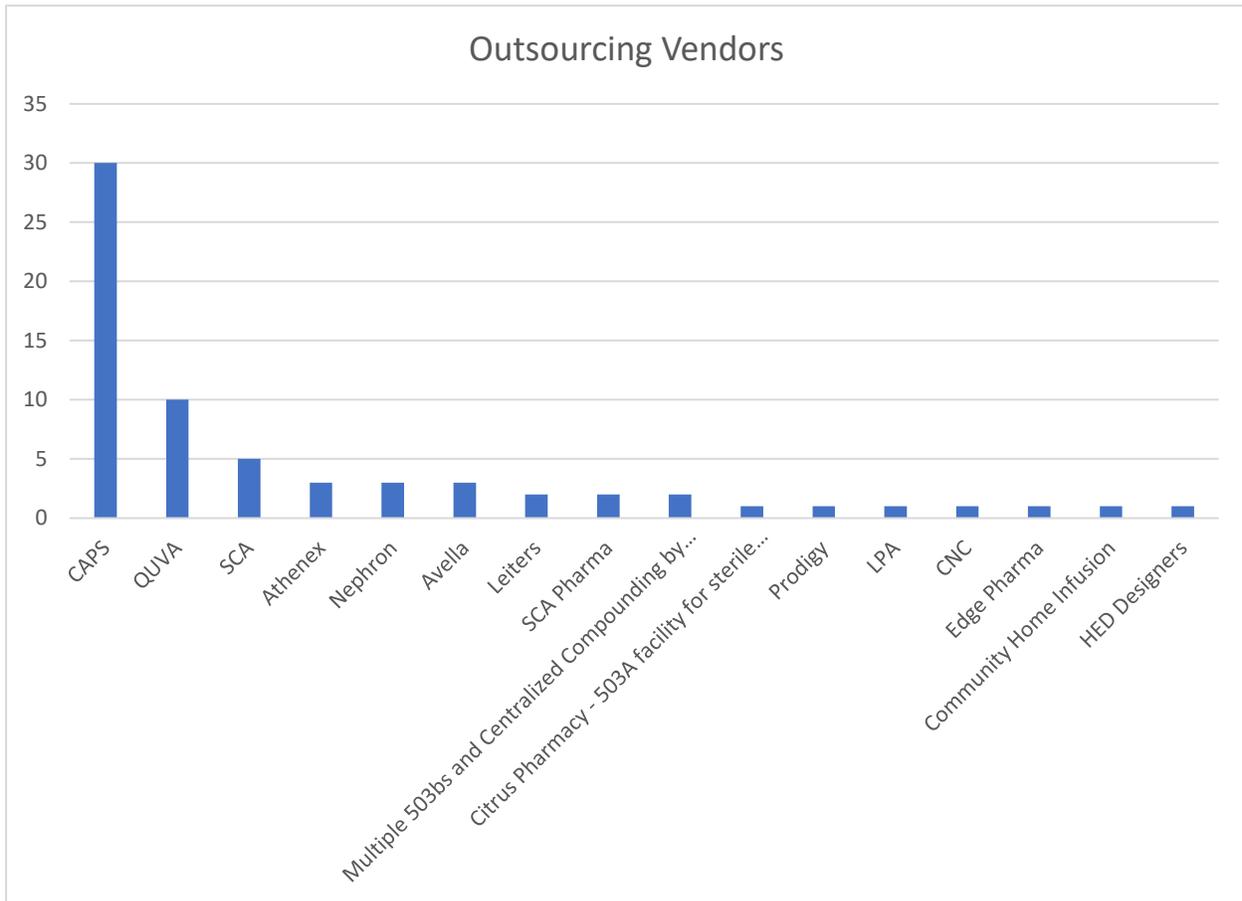


ANSWER CHOICES	RESPONSES
Financial constraints	41.89% 62
Inability to get skilled contractor and/or architects	15.54% 23
Construction supply line issues	14.19% 21
No longer planning to perform sterile compounding on site	0.68% 1
Other (please specify)	Responses 68.24% 101
Total Respondents: 148	

- Financial constraints were identified as a major reason for construction delays.
- The inability to get skilled contractors and/or architects, along with construction supply line issues, each represented less than 20% (23 and 21) as reasons for delays in construction.
- For respondents listing “other” for delays, most have not yet decided whether or when to begin construction (see graph below).



Question #3 - If outsourcing, please identify outsourcing vendor



- Almost 45% (30) of respondents identified CAPS as their chosen vendor for outsourcing sterile compounded pharmaceuticals.

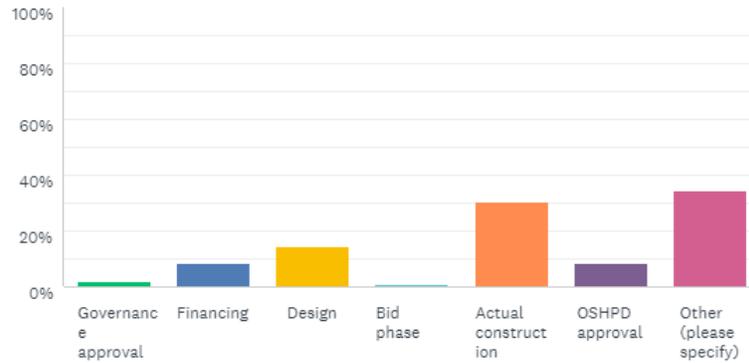
Question #4 - Is a mobile sterile compounding unit currently being used or in the plans for future use?

- 8% (16) are using a mobile sterile compounding unit.

Questions #5 – If construction is underway, please identify where you are in the current process.

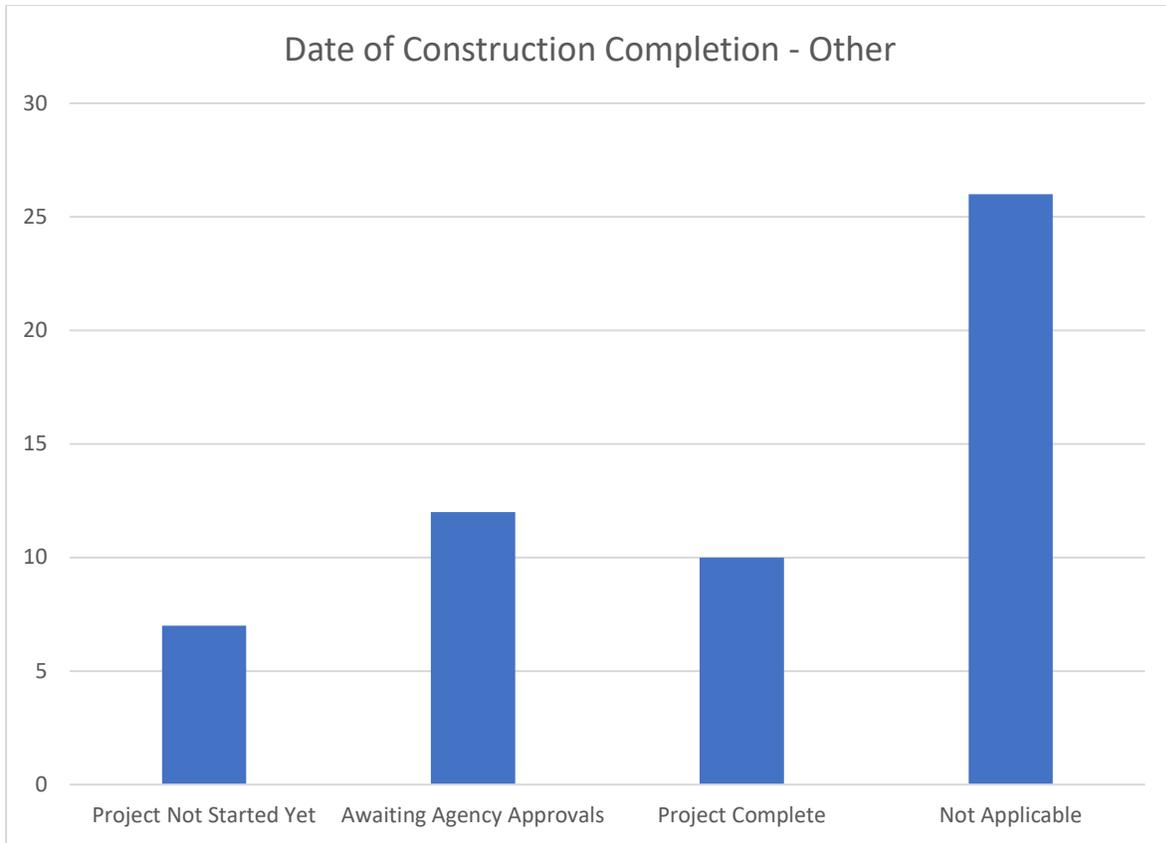
If construction is underway, please identify where you are in the current process.

Answered: 160 Skipped: 47

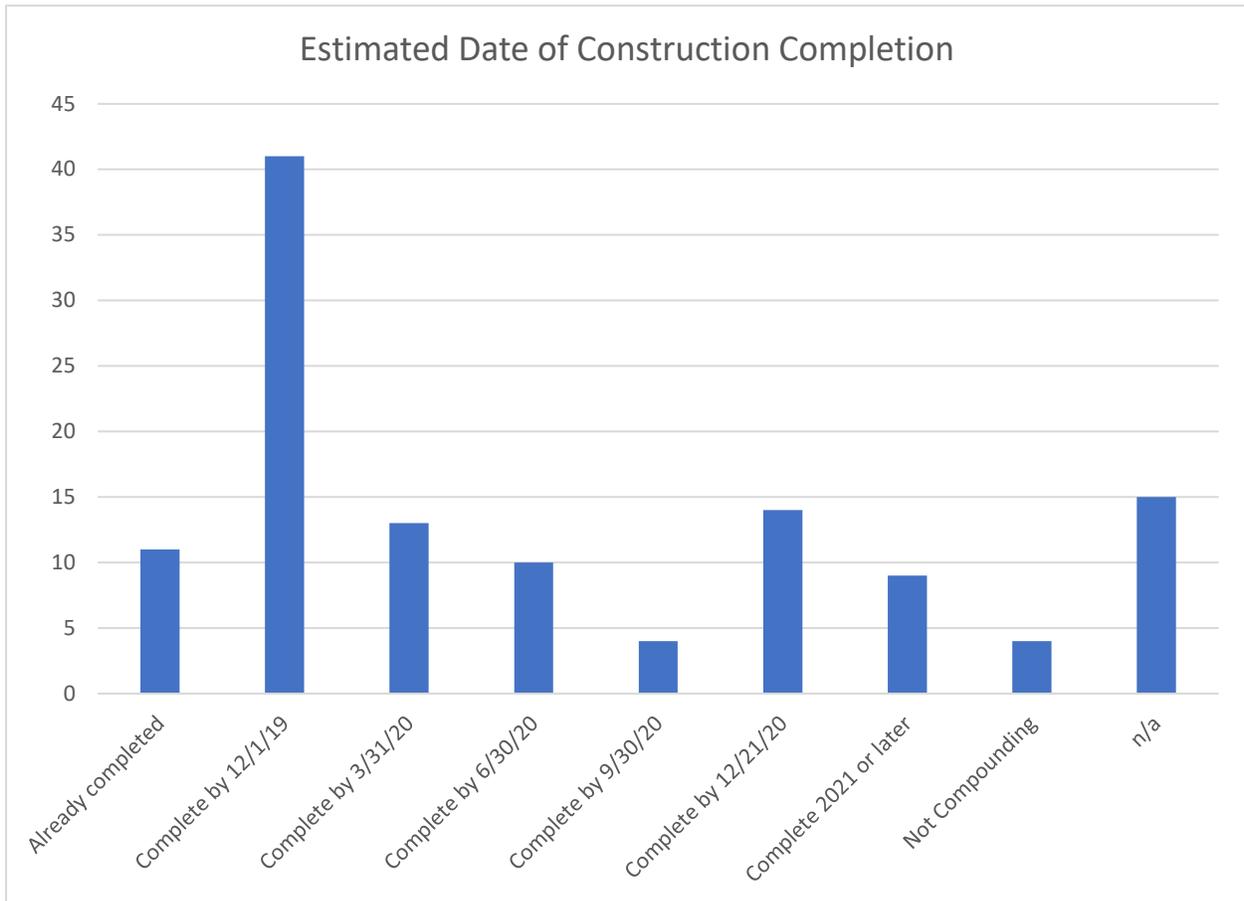


ANSWER CHOICES	RESPONSES
▼ Governance approval	1.88% 3
▼ Financing	8.75% 14
▼ Design	14.37% 23
▼ Bid phase	1.25% 2
▼ Actual construction	30.63% 49
▼ OSHPD approval	8.75% 14
▼ Other (please specify) Responses	34.38% 55
TOTAL	160

- Most respondents have already begun the actual construction process.
- Of those who answered “other”, 22% (12) are awaiting agency approval (see graph below).



Question #6 – What is the estimated date of construction completion?

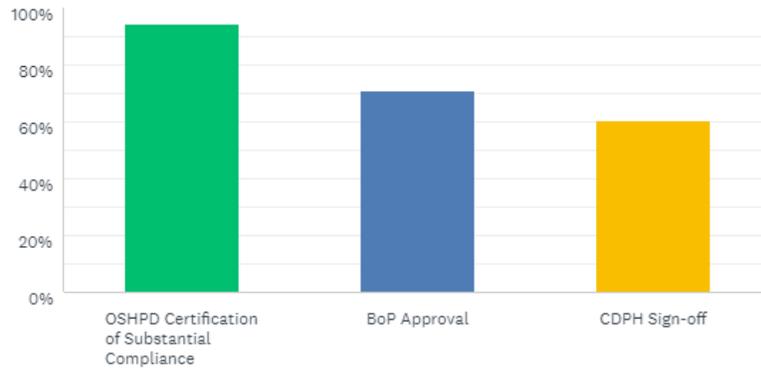


- Almost 34% (41) indicated that construction would be complete by the December 1, 2019 deadline.
- Another 34% (41) anticipate construction completion by the end of 2020.

Question #7 - If construction is complete, have the following approvals been obtained?

If construction is complete, have the following approvals been obtained?
(Check all that apply).

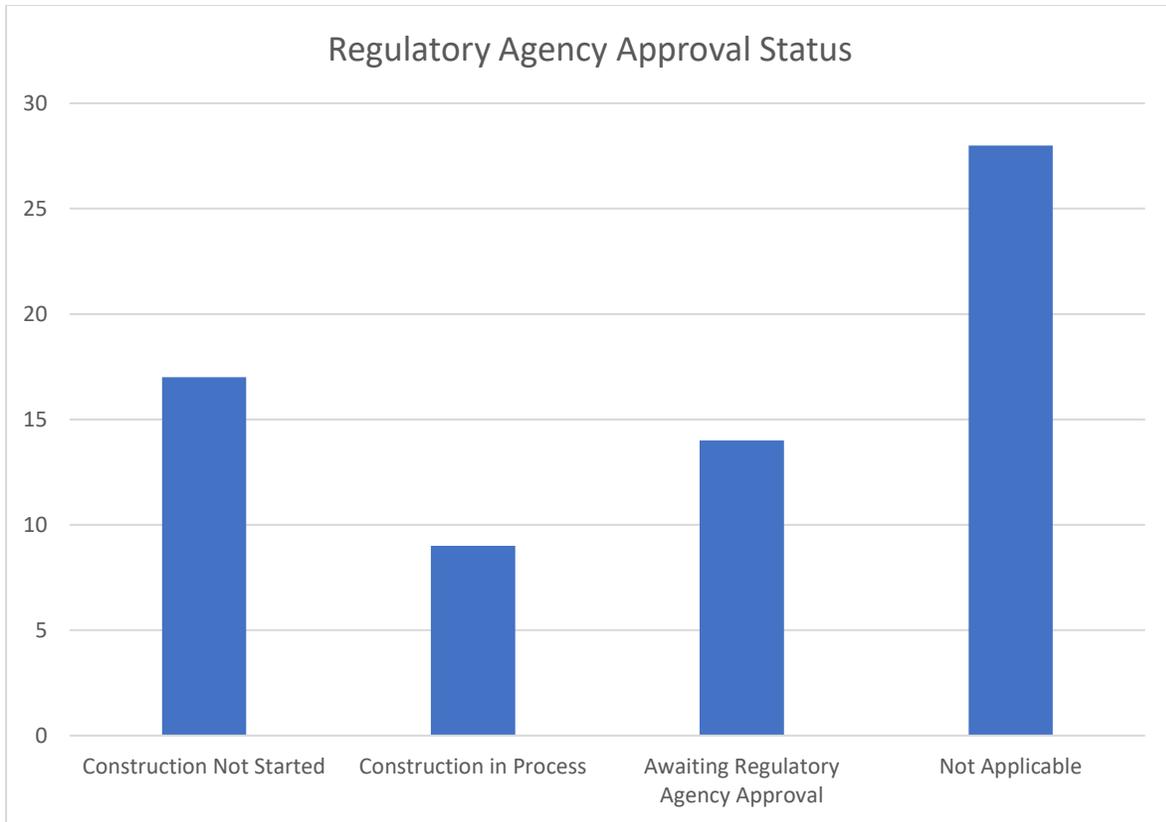
Answered: 38 Skipped: 170



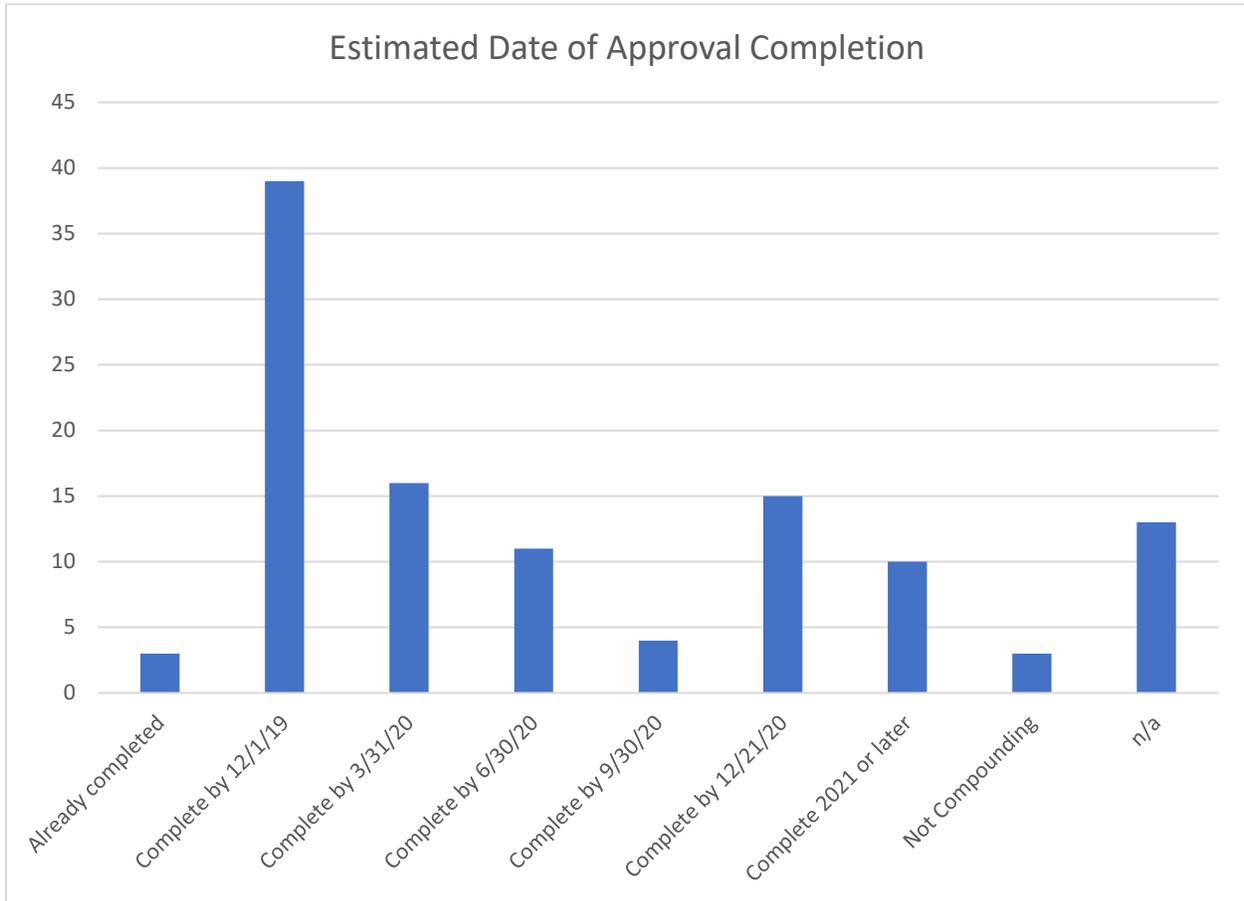
ANSWER CHOICES	RESPONSES
OSHPD Certification of Substantial Compliance	94.74% 36
BoP Approval	71.05% 27
CDPH Sign-off	60.53% 23
Total Respondents: 38	

[Comments \(68\)](#)

- Almost 95% (36) who have completed construction have also received OSHPD approval.



Question #8 – What is your estimated target date for all the following to be completed: OSHPD, BoP, and CDPH approvals?

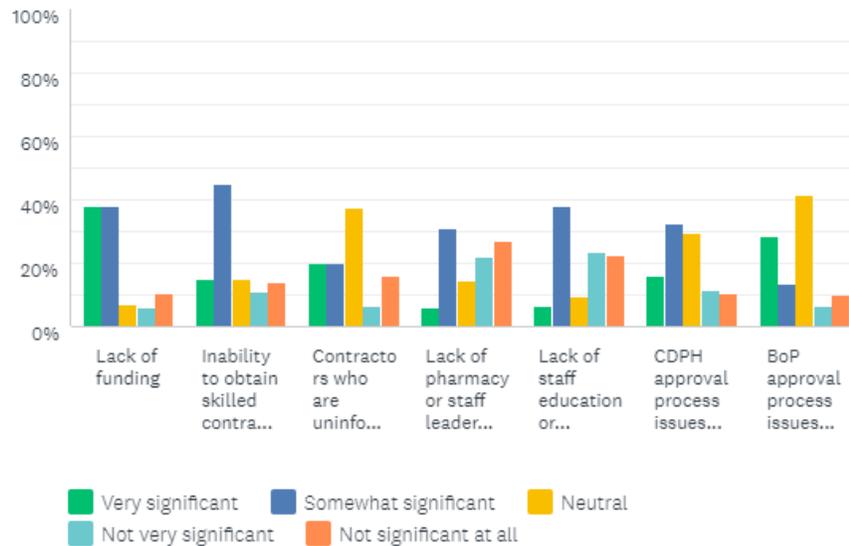


- Over a third (39) of respondents anticipate having construction completed and all regulatory approvals by the December 1, 2019 deadline.
- Of those missing the deadline, 40% (46) expect to be complete by the end of 2020.

Question #9 – Please identify the most significant barriers to timely completion

Please identify the most significant barriers to timely completion. (Check all that apply and rank)

Answered: 181 Skipped: 27



- Lack of funding was identified by more than 75% (128) of respondents as a significant barrier to timely completion.
- The inability to obtain skilled contractors and/or architects was also listed by over 60% (104) as a barrier.
- A lack of pharmacy or staff leadership to fully inform the process change was seen as the least significant barrier to timely completion of the project (49%) (82).

	VERY SIGNIFICANT	SOMEWHAT SIGNIFICANT	NEUTRAL	NOT VERY SIGNIFICANT	NOT SIGNIFICANT AT ALL	TOTAL
▼ Lack of funding	38.10% 64	38.10% 64	7.14% 12	5.95% 10	10.71% 18	168
▼ Inability to obtain skilled contractors and/or architects	15.03% 26	45.09% 78	15.03% 26	10.98% 19	13.87% 24	173
▼ Contractors who are uninformed of the USP standards	20.12% 34	20.12% 34	37.28% 63	6.51% 11	15.98% 27	169
▼ Lack of pharmacy or staff leadership to fully inform the process change	5.95% 10	30.95% 52	14.29% 24	22.02% 37	26.79% 45	168
▼ Lack of staff education or understanding regarding USP requirements to adequately oversee the project	6.47% 11	38.24% 65	9.41% 16	23.53% 40	22.35% 38	170
▼ CDPH approval process issues, if so please explain in comment section	16.18% 28	32.37% 56	29.48% 51	11.56% 20	10.40% 18	173
▼ BoP approval process issues, if so please explain in comment section	28.65% 49	13.45% 23	41.52% 71	6.43% 11	9.94% 17	171