# USP Open Forum | Excipients

## Review of Excipient Impurities Survey Responses

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# Excipient impurities 2018 Survey

## Specific survey objectives:

1. To identify overall needs and challenges regarding the current written standards (monographs and *General Notices*) on impurities in excipients
2. To assess the level of satisfaction with the current written standards on impurities for excipients
3. To identify opportunities for improvement
4. To analyze input on modernizing documentary standards on impurities in excipients
5. To receive feedback on the proposed definitions and approach for setting specifications for excipient components

# Excipient impurities 2018 Survey summary

1. Most respondents (87%) believe that updating USP specifications for excipient composition and impurities is important.

2. Specific impurities tests in monographs are the most commonly used USP-NF resources for testing impurities in excipients (by nearly 8 in 10).
    - About a quarter “never use” General Notices 5.60 on Impurities and Degradation Products.

3. Nearly all respondents agreed with the proposed definitions in the *Stimuli* article for “Simple Excipient”, “Nominal Component”, and “Added Substances in Official Substances”.

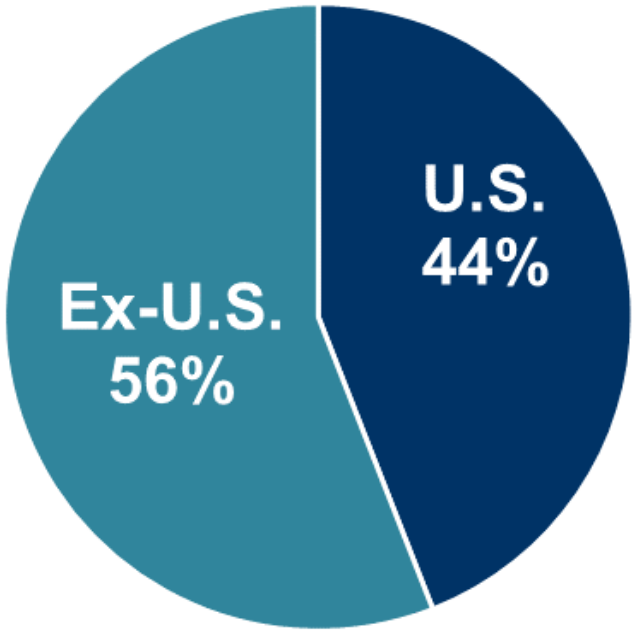
4. More than 6 in 10 respondents said that General Notices 5.60.10 *Other impurities* in USP and NF articles should be updated/clarified.

5. Pharmacopeial methods are most commonly used by respondents to test excipients for specific impurities specifications, followed by in-house procedures.
    - COAs and Outsourced Testing are less frequently used.

6. Nearly all respondents would support updating USP-NF to allow use of alternative testing options in the monograph, when one standard cannot be used for a particular material.

7. Three quarters of respondents would be interested in training from USP if a USP-NF general chapter on impurities for excipient were developed.

# Overall Respondent Profile: Regions

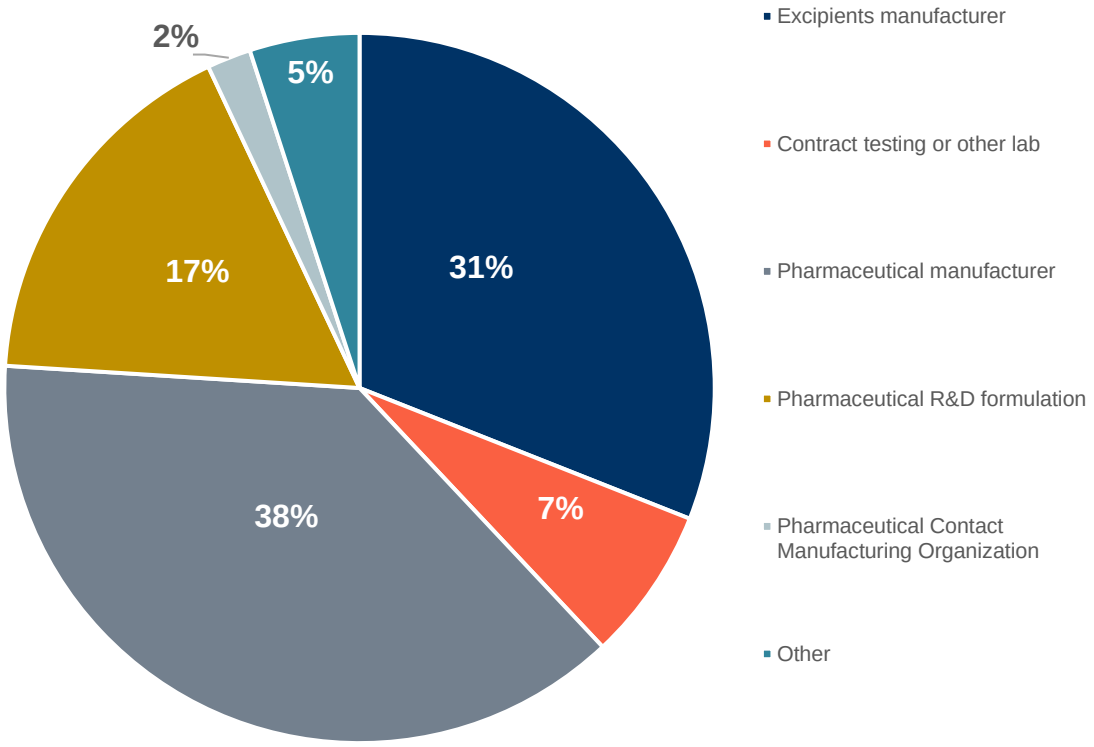



| Top Geographic Regions<br>By Frequency of Survey Response | | |
|---|---|---|
| | Count | % |
| United States | 15 | 44 |
| China/Taiwan | 1 | 3 |
| India | 8 | 24 |
| Brazil | 2 | 6 |
| Germany | 3 | 9 |
| South Korea | 1 | 3 |
| United Kingdom | 2 | 6 |
| Other | 2 | 6 |

*Please select the country in which you work. (n=34)*

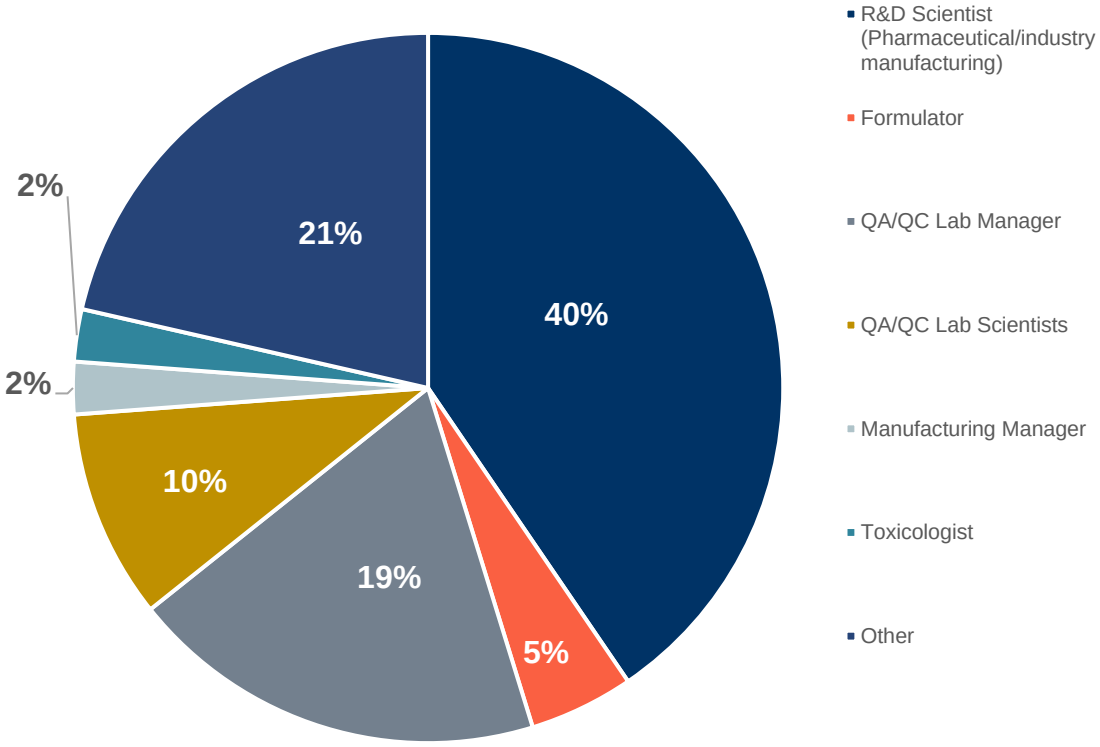
# Overall Respondent Profile: Company Type and Role

## Type of Company for Which Respondent Works



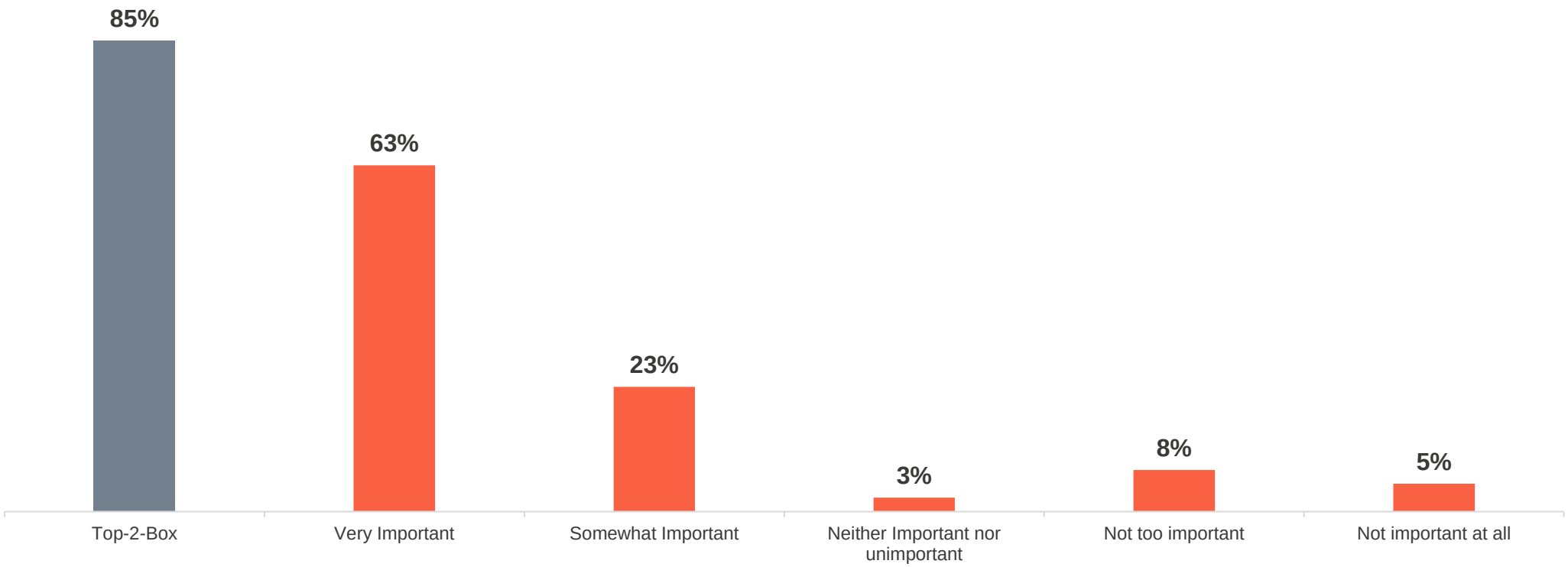

*Q5 Please describe your organization/company for which you work (n=42)*

## Primary Role at Company



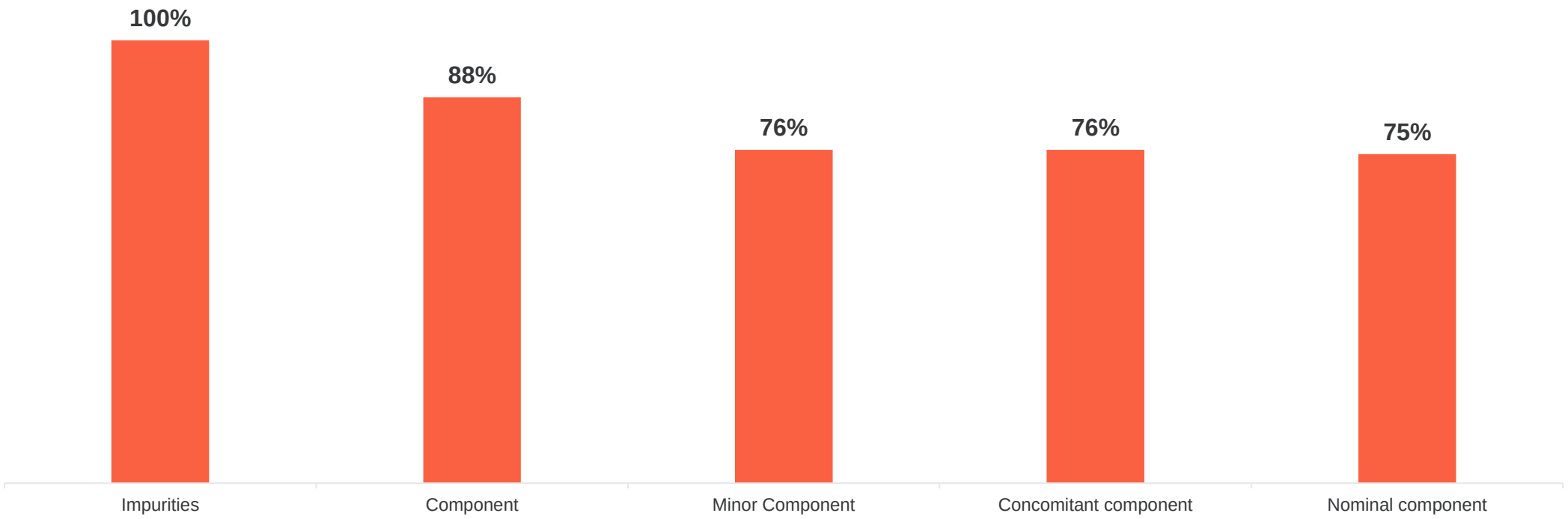

*Q6 What is your primary role at your company? (n=42)*

# 85% said it is very/somewhat important to update USP specifications for excipient composition and impurities



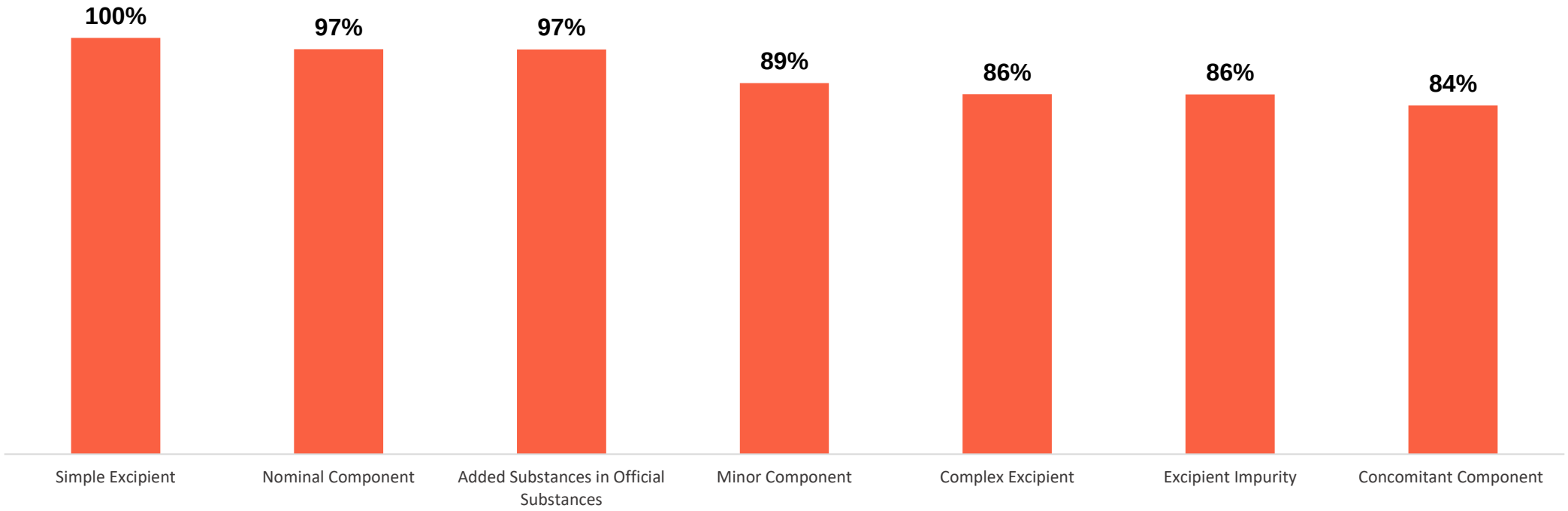

*Q9 In your opinion, how important is updating USP compendial specifications for excipient composition and impurities for determining the quality of pharmaceutical excipients?* ***"Top-2-Box" percent reflects top-two scores (5 & 4) on a 5-point "Importance" scale.*** *(n=40)*

# 88% or more were very/somewhat familiar with the terms “component” and “impurities” for describing excipient composition



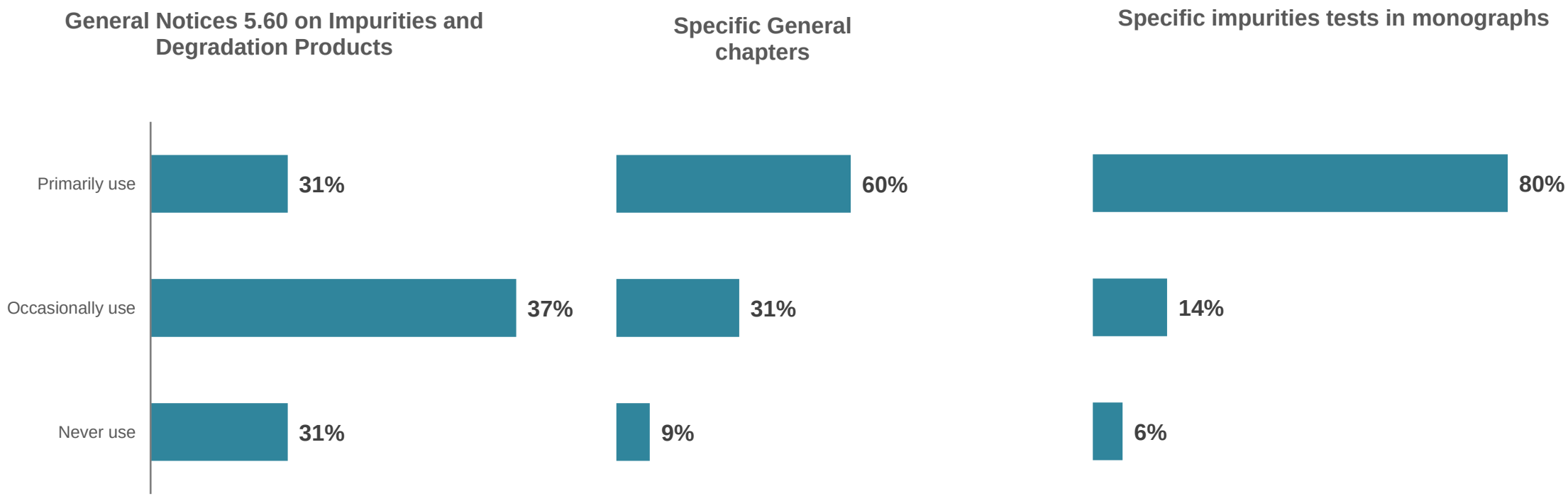

*Q10 To what extent are you familiar with the following terms, component, nominal component, concomitant component, impurities, and minor component for describing excipient composition?* ***Findings reflect top-two scores (4 & 3) on a 4-point “Familiar” scale.*** *(n=40)*

# Nearly all respondents agreed with the proposed definitions for Simple Excipient, Nominal Component, and Added Substances in Official Substances



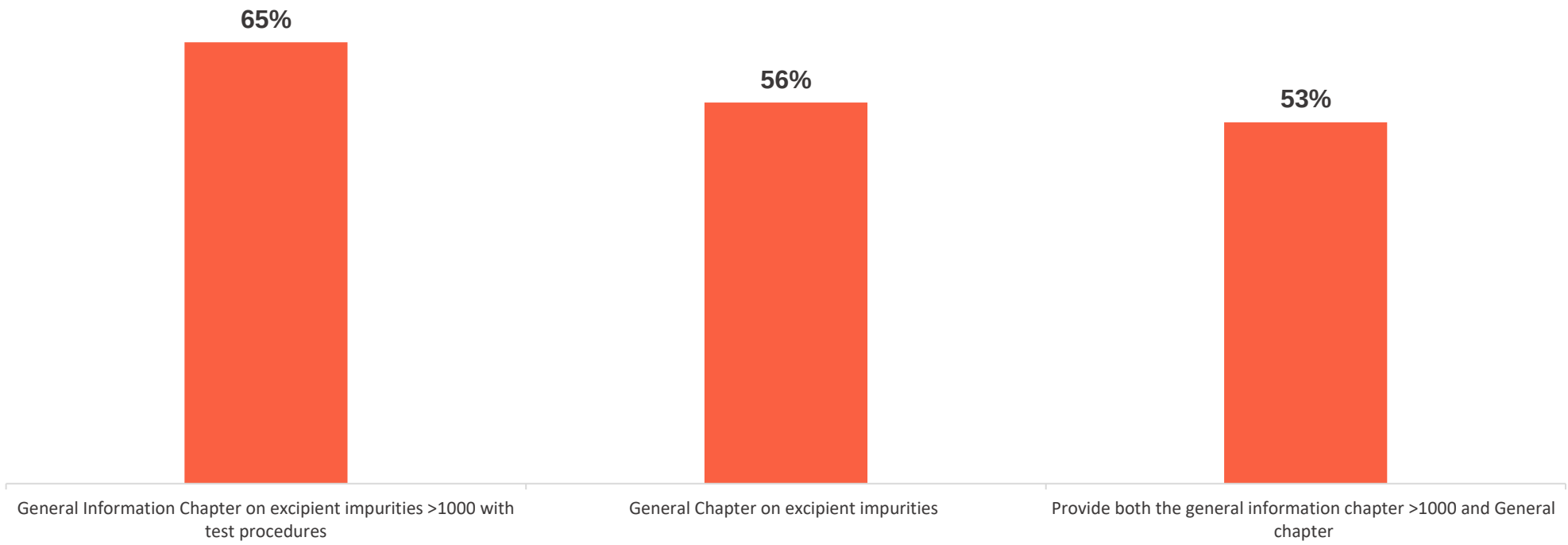

*Q11 Please indicate your level of agreement with the following USP Pharmacopeial definitions for a pharmaceutical excipient proposed in the Stimuli article published in Pharmacopeial Forum (PF) 44(3).* ***Findings reflect top-two scores (4 & 3) on a 4-point "Agree" scale.*** *(n=37)*

# Specific impurities tests in monographs are the most commonly used USP-NF resources for testing impurities in excipients



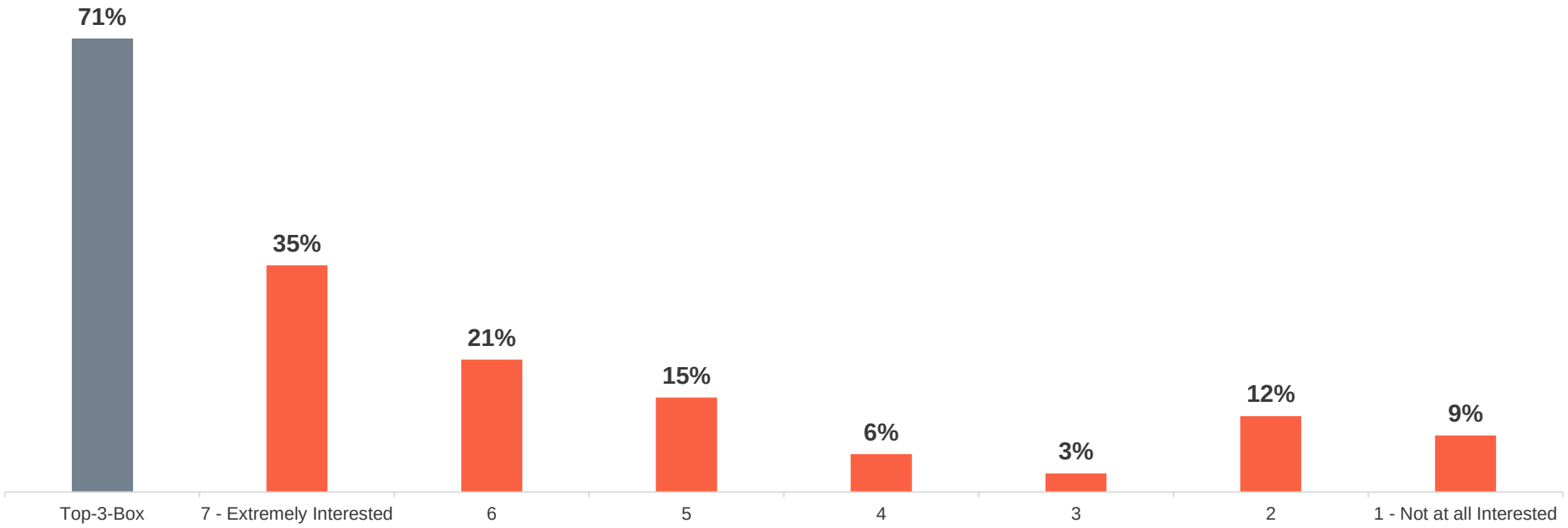

*Q14 To what extent do you use each of the following USP-NF resources primarily for testing impurities in pharmaceutical excipients? (n=35)*

# 65% supported the development of a general chapter on excipient impurities >1000 with test procedures




*Q18 Please indicate your level of support for USP's development of a General Chapter on Impurities in Pharmaceutical Excipients from the following options.* ***Findings reflect top-three scores (7, 6 & 5) on a 7-point "Supportive" scale.*** *(n=34)*

# 71% would be interested in training from USP if a USP-NF general chapter on impurities for excipient were developed




*Q21 If a USP-NF General Chapter on impurities for excipient is developed, how interested would you be in taking training from USP on the new standard?* ***"Top-3-Box" percent reflects top-three scores (7, 6 & 5) on a 7-point "Interested" scale.*** *(n=34)*

# 2021 Survey on Complexities of setting compendial specifications for Excipient composition and impurities – Organic impurities

Understanding importance and impact of establishing compositional and impurity specifications in excipient monographs

# Q1: Please indicate if you are:

- Answered: 83 Skipped: 0

| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Excipient maker | 27.71% | 23 |
| Pharmaceutical manufacturer (Excipient end user) | 34.94% | 29 |
| Formulator/Drug developer | 8.43% | 7 |
| Contract Manufacturer (CMO) | 1.20% | 1 |
| Contract Analytical Laboratory (CAL) | 4.82% | 4 |
| Excipient supplier | 1.20% | 1 |
| Distributor | 0.00% | 0 |
| Other (please specify) | 21.69% | 18 |
| TOTAL | | 83 |

# Q2: If USP introduces impurity tests/ levels to reflect use in currently regulated /marketed drug products that are consistent with levels identified using optimal analytical testing, will this cause a problem at the end user level?

- Answered: 39 Skipped: 44

| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Very likely | 20.51% | 8 |
| Likely | 33.33% | 13 |
| Neither likely nor unlikely | 30.77% | 12 |
| Unlikely | 15.38% | 6 |
| Very unlikely | 0.00% | 0 |
| TOTAL | | 39 |

# Q3: If USP consistently moves away from wet chemistry tests to instrumentation-based tests, will this have a significant financial impact on testing for USP monographs?

- Answered: 39 Skipped: 44

| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Very likely | 20.51% | 8 |
| Likely | 46.15% | 18 |
| Neither likely nor unlikely | 17.95% | 7 |
| Unlikely | 15.38% | 6 |
| Very unlikely | 0.00% | 0 |
| TOTAL | | 39 |

# Q4: Do you consider testing that helps understand excipient composition necessary analytical testing?

- Answered: 38 Skipped: 45

| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Yes | 71.05% | 27 |
| No | 5.26% | 2 |
| Maybe | 23.68% | 9 |
| TOTAL | | 38 |

# Q5: Do you consider compositional testing IMPORTANT for controlling the risk of contamination and adulteration?

- Answered: 39 Skipped: 44

| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Yes | 76.92% | 30 |
| No | 7.69% | 3 |
| Maybe | 15.38% | 6 |
| TOTAL | | 39 |

# Q6: Do you consider testing for excipient organic impurities necessary analytical testing?

- Answered: 39 Skipped: 44

| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Yes | 46.15% | 18 |
| No | 7.69% | 3 |
| Maybe | 46.15% | 18 |
| TOTAL | | 39 |

# Q7: Please select who performs the excipient testing?

- Answered: 76 Skipped: 7

| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Excipient maker | 42.11% | 32 |
| Contract Analytical Laboratory (CAL) | 6.58% | 5 |
| Contract Manufacturer (CMO) | 1.32% | 1 |
| Pharmaceutical manufacturer (Excipient end user) | 30.26% | 23 |
| Formulator/Drug developer | 2.63% | 2 |
| Other (please specify) | 17.11% | 13 |
| TOTAL | | 76 |

# Q8: How often is excipient testing performed?

- Answered: 75 Skipped: 8

| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Weekly | 24.00% | 18 |
| Monthly | 8.00% | 6 |
| Quarterly | 10.67% | 8 |
| Yearly | 16.00% | 12 |
| Other (please specify) | 41.33% | 31 |
| TOTAL | | 75 |

# Thank You

# Stay Connected

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