

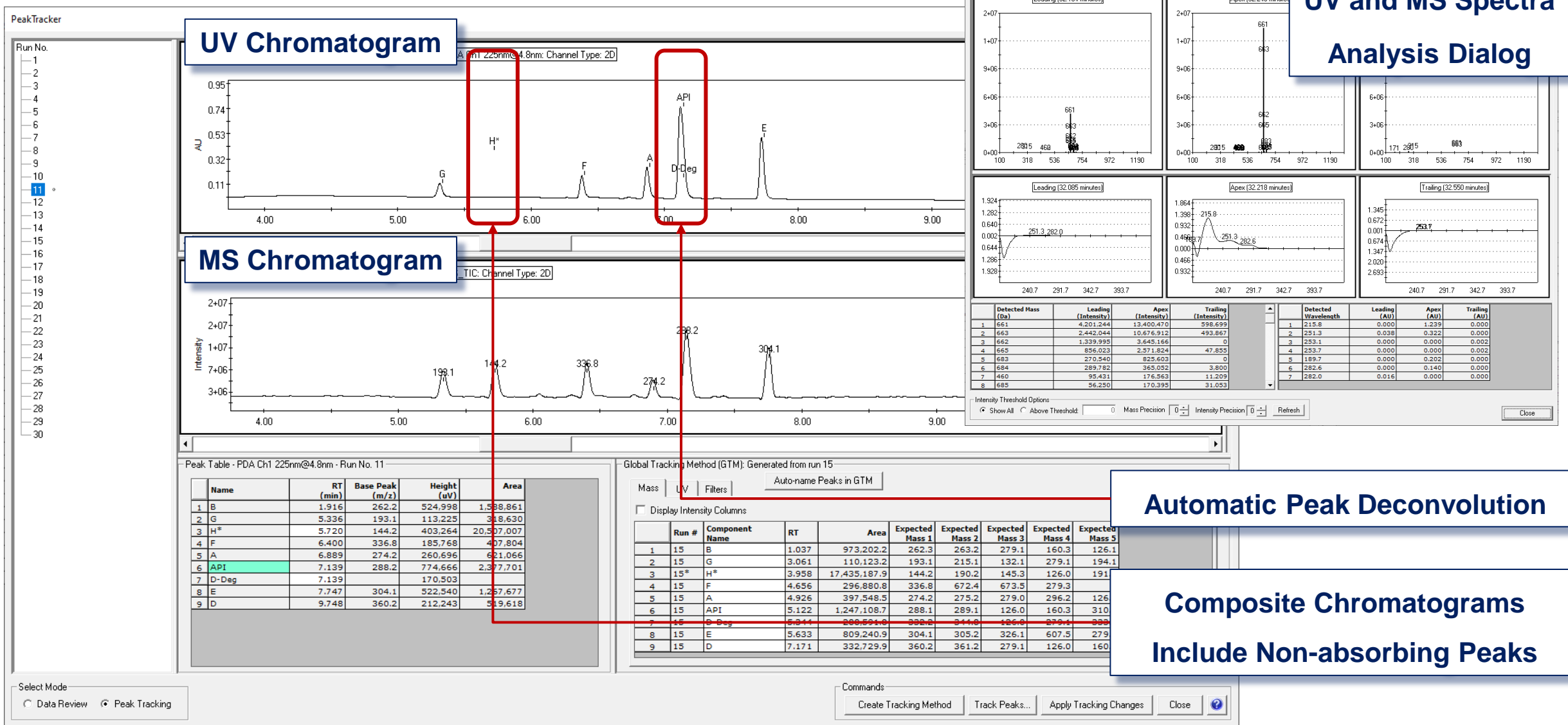


Fusion QbD[®]

UV & MS Spectra Based Peak Tracking



PeakTracker™ – UV & MS Spectra-based Tracking





PeakTracker – Row 15 Elution Order

| Run 15 - Global Tracking Method | | |
|---------------------------------|----------------|-----------------|
| | Component Name | Expected Mass 1 |
| 1 | B | 262.2 |
| 2 | G | 193.1 |
| 9 | H* | 144.2 |
| 3 | F | 336.8 |
| 4 | A | 274.1 |
| 5 | API | 288.1 |
| 6 | D-Deg | 332.1 |
| 7 | E | 304.1 |
| 8 | D | 360.2 |

Co-eluted Peak Deconvolution in Run 10

PeakTracker – Run 10:

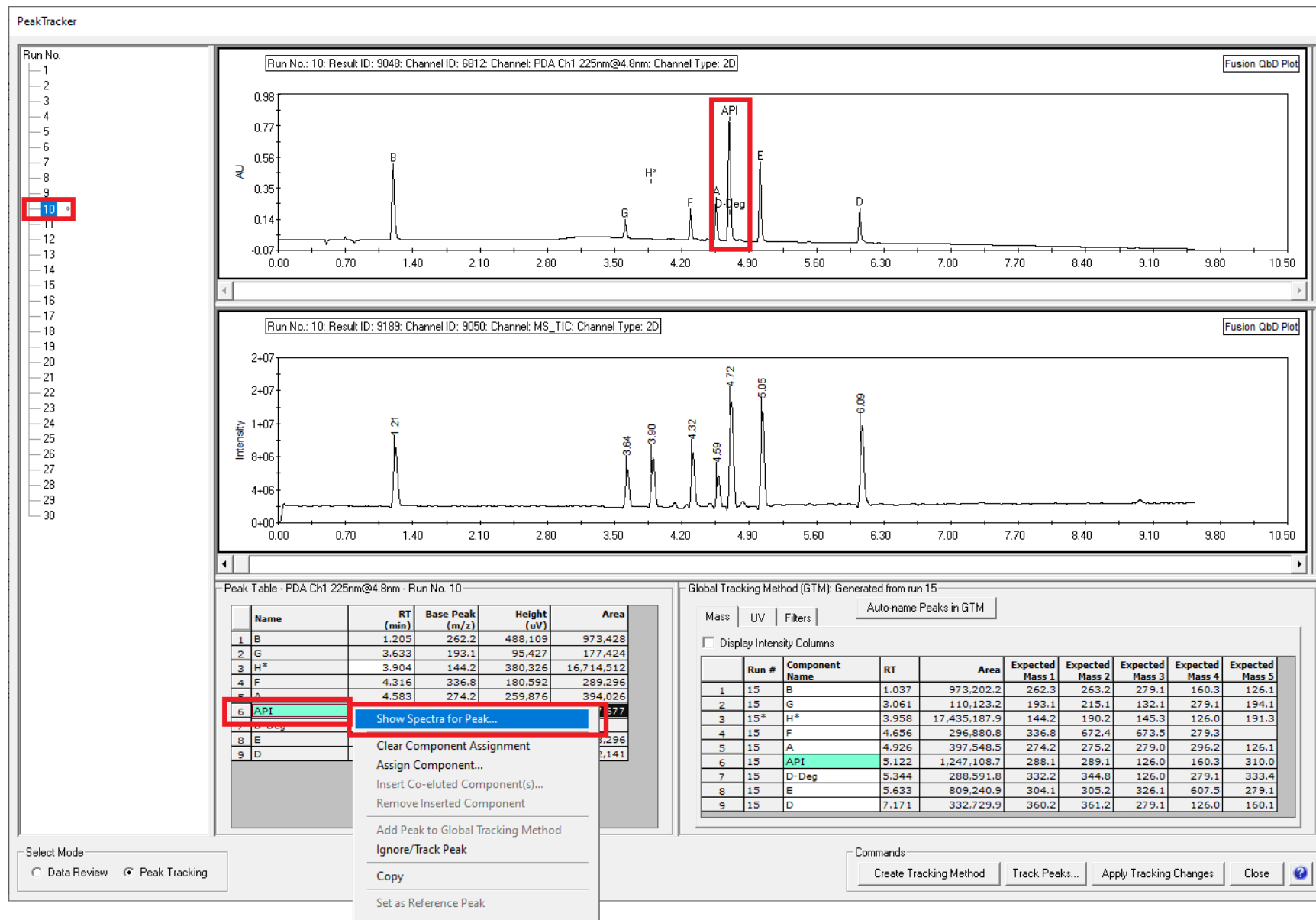
- D-Deg is Missing in Data Chromatogram because it is Co-eluted with the API.
- PeakTracker Located the D-Deg peak under the API (Go to 2 Next Slides to See Why).



Access MS Spectra for the API Peak

PeakTracker – Run 10:

- Select the API peak in the Peak Table.
- Right click to launch the popup menu.
- Select the “Show Spectra for Peak” option.





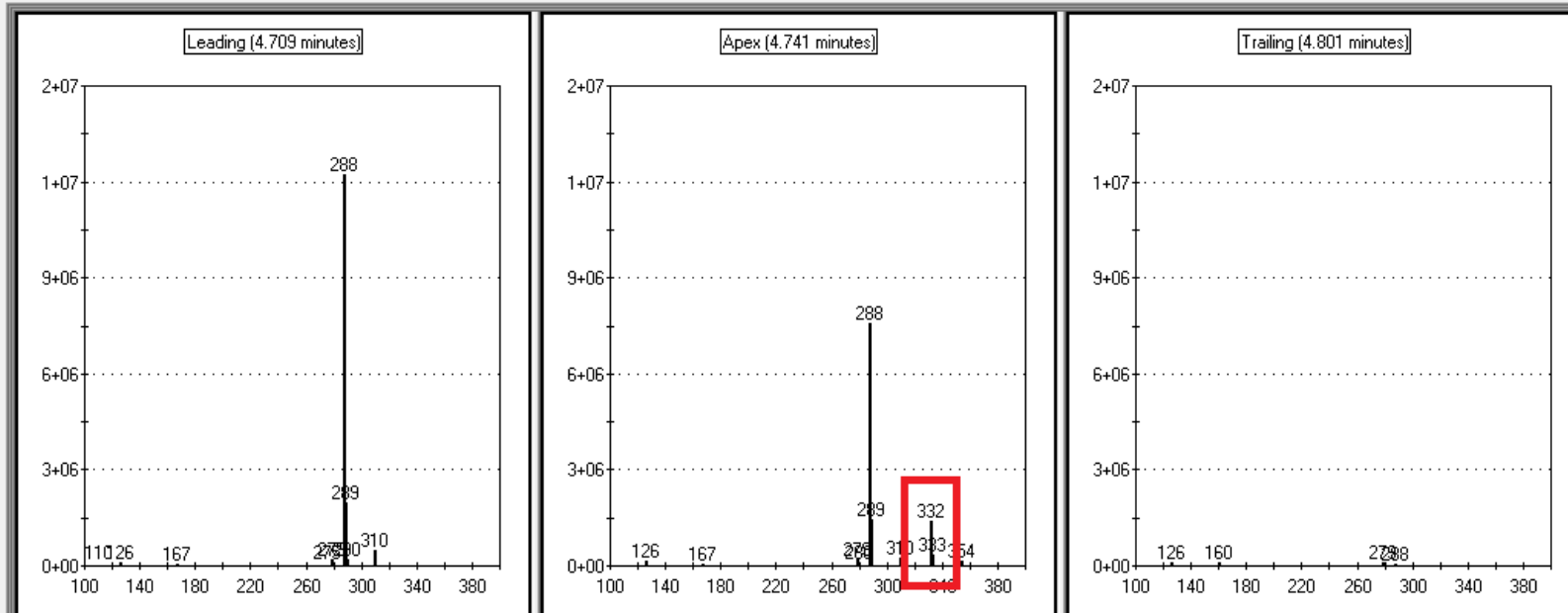
Examine MS Spectra for the API Peak

MS Spectra Analysis –

API peak – Run 10:

- See the base peak value for the D-Deg peak (332) within the Apex spectra for the API.

Extracted Spectra: Row 6 (API)



| | Detected Mass (Da) | Leading (Intensity) | Apex (Intensity) | Trailing (Intensity) |
|----|--------------------|---------------------|------------------|----------------------|
| 1 | 288 | 12,206,700 | 7,564,340 | 56,641 |
| 2 | 289 | 1,868,410 | 1,425,061 | 0 |
| 3 | 332 | 0 | 1,380,625 | 0 |
| 4 | 333 | 0 | 320,410 | 0 |
| 5 | 310 | 469,797 | 260,570 | 0 |
| 6 | 279 | 175,391 | 186,231 | 115,438 |
| 7 | 126 | 101,943 | 150,948 | 119,420 |
| 8 | 354 | 0 | 125,457 | 0 |
| 9 | 280 | 0 | 79,750 | 0 |
| 10 | 167 | 54,706 | 70,066 | 0 |
| 11 | 110 | 76,520 | 0 | 0 |

Intensity Threshold Options:

☒ Show All

☐ Above Threshold:

0

Mass Precision 0

Intensity Precision 0

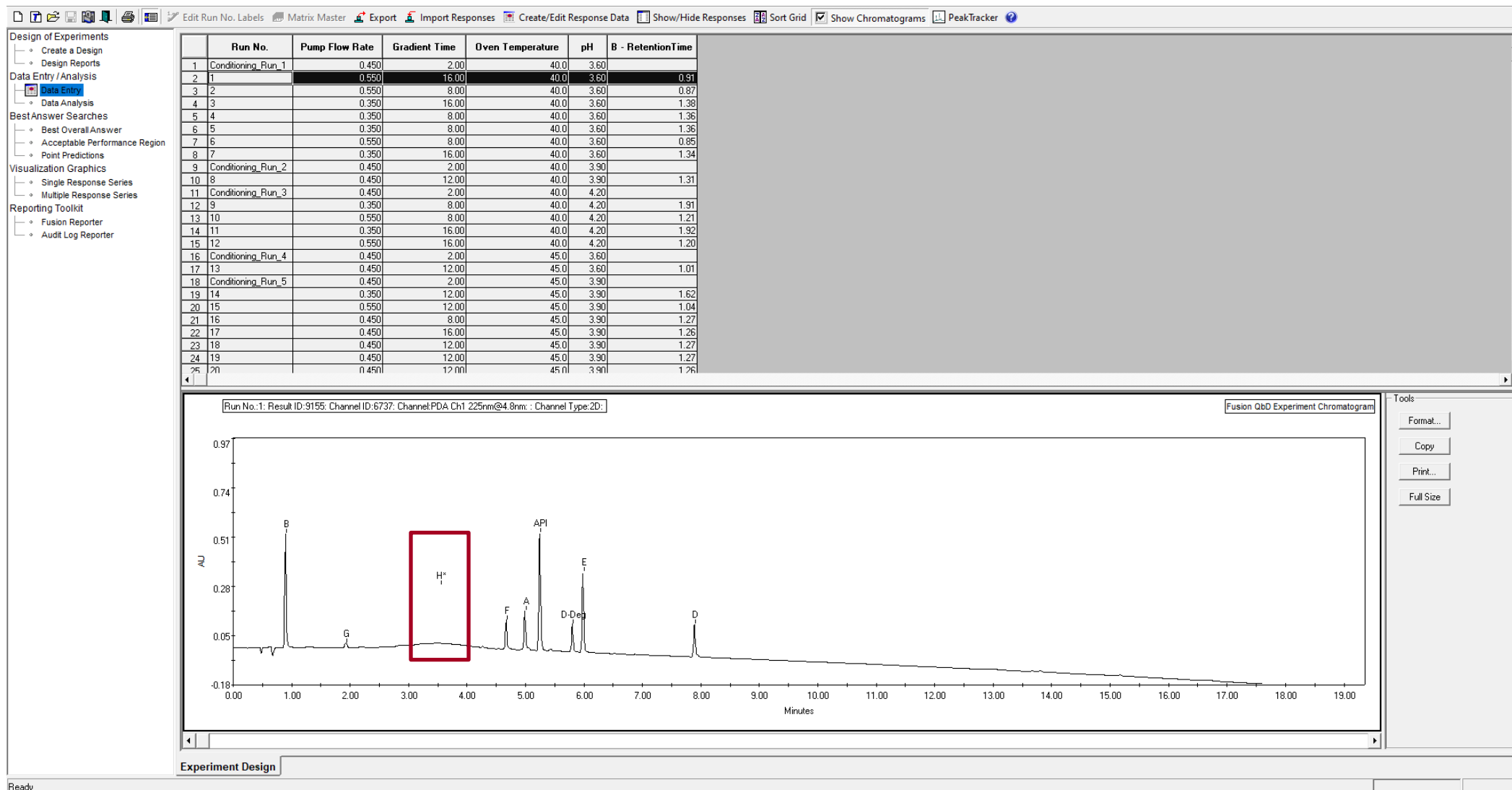
Refresh

Close



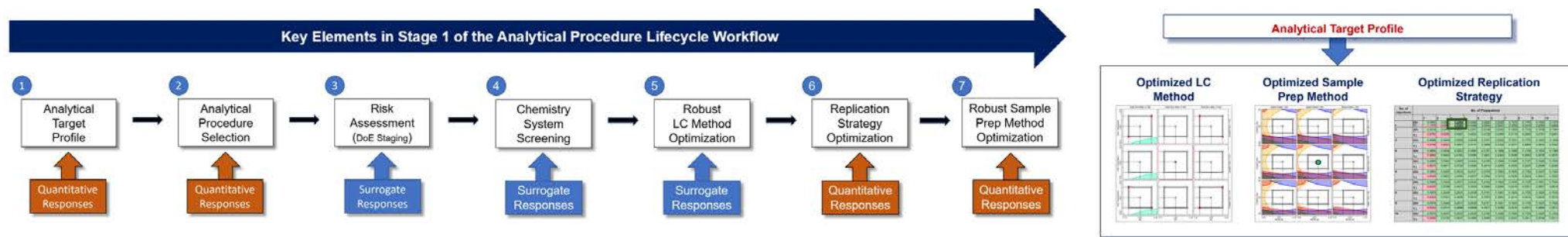
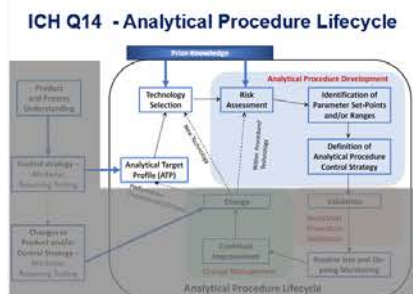
Evaluate Data Completeness

Peaks are Identified and Tracked. Non-absorbing Compound H* is now Present in the UV Chromatograms.



End of Presentation

Fusion QbD is the Only LC Method Development Software Which Completely Supports the AQbD / APLM Workflow in the Regulatory Guidances



ICH Q2(R2) / ICH Q14 / USP <1210> / USP <1220> / EP 11.60