Case Studies from Analytical Method Technology Transfer Studies: Learning from Experience

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JPAG Symposium: Analytical Method Technology Transfers

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Analytical Method Transfer

Learning from Experience

- → A risk based approach enables the selection of the most appropriate experiments during transfer.
- → Each transfer situation is slightly different and therefore different approaches may be taken.
- → Issues may arise that are particular to that transfer and may not have been experienced before.
- → It is very useful to learn from experience to avoid future issues.
  - Preferably other people's!
- → Aim of this presentation is to provide useful information for consideration during method transfer studies.

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ICH Q2(R2)- 2.2 Validation During the Lifecycle of an Analytical Procedure

'Transfer of a validated analytical procedure should be considered in the context of analytical lifecycle changes in line with ICH Q14. When transferring analytical procedures to a different laboratory, a partial or full revalidation of the analytical procedure performance characteristics and/or comparative analysis of representative samples should be performed. Justification for not performing additional transfer experiments should be provided if appropriate.'

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ICH Q14 - 7. LIFECYCLE MANAGEMENT AND POST-APPROVAL CHANGES OF ANALYTICAL PROCEDURES

Table 2: Examples of analytical procedure change evaluation

Risk Factor: Extent of change	Bridging strategy	Evidence of the suitability of a new procedure
Transfer of analytical procedure to a different site with no change in procedure itself	Partial or full revalidation of the analytical procedure performance characteristics And/or Comparative analysis of representative samples and reference materials Or Justification for not performing additional transfer experiments	Analytical procedure attributes are evaluated and criteria are met after change And/or Results are comparable

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Method Transfer Definition:

USP <1224>

"The transfer of analytical procedures (TAP), also referred to as method transfer, is the documented process that qualifies a laboratory (the receiving unit) to use analytical test procedure that originated in another laboratory (the transferring unit, also referred to as the sending unit), thus ensuring that the receiving unit has the procedural knowledge and ability to perform the transferred analytical procedure as intended."

LABORATORY 1
Sending Unit

LABORATORY 2
Receiving Unit

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CASE STUDY 1

METHOD: Assay of a drug product (capsules)

A set of 15 results was generated in each of two laboratories for the transfer

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Results:

(% Label Claim)

	Sending Unit			Receiving Unit		
	1	2	3	4	5	6
1	98.641	98.711	98.986	99.000	99.000	98.500
2	99.023	98.622	98.316	100.500	99.000	99.500
3	98.780	98.742	98.522	98.000	98.500	97.500
4	98.961	98.560	98.653	100.170	98.000	97.500
5	98.628	98.717	98.732	99.000	99.000	99.000

- → What does the data relate to? We don't know how the data has been generated.
- → All of the values are given to 3 decimal places.
- → Appears to be a difference in terms of significant figures.
- → The range of data is from 97.500 to 100.50

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Results:

(% Label Claim)

	Sending Unit			Receiving Unit		
	Run 1	Run 2	Run 3	Run 4	Run 5	Run 6
1	98.641	98.711	98.986	99.000	99.000	98.500
2	99.023	98.622	98.316	100.500	99.000	99.500
Independent preparations 3	98.780	98.742	98.522	98.000	98.500	97.500
4	98.961	98.560	98.653	100.170	98.000	97.500
5	98.628	98.717	98.732	99.000	99.000	99.000

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Types of Test Method Replicates:

1. Independent preparations
   - Multiple full analyses of the same homogenous sample.
2. Replicates within the method
   - Measurements, e.g., multiple injections
   - Sub-aliquots of original sample aliquot

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Results:

(% Label Claim)

		Sending Unit			Receiving Unit		
		Run 1	Run 2	Run 3	Run 4	Run 5	Run 6
Independent preparations	1	98.641	98.711	98.986	99.000	99.000	98.500
	2	99.023	98.622	98.316	100.500	99.000	99.500
	3	98.780	98.742	98.522	98.000	98.500	97.500
	4	98.961	98.560	98.653	100.170	98.000	97.500
	5	98.628	98.717	98.732	99.000	99.000	99.000

→ Do all replicates relate to the same batch of material?

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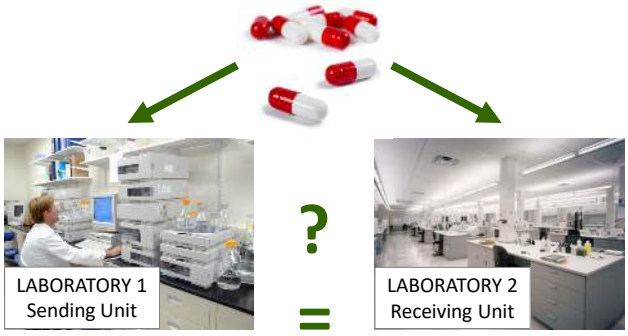
Comparative Testing in Transfer

Testing is performed by both laboratories on a homogeneous lot of the target material.



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Results:

(% Label Claim)

	Sending Unit			Receiving Unit		
	Analyst 1 Day 1 Run 1	Analyst 2 Day 1 Run 2	Analyst 2 Day2 Run 3	Analyst 3 Day 1 Run 4	Analyst 4 Day 1 Run 5	Analyst 4 Day 2 Run 6
1	98.641	98.711	98.986	99.000	99.000	98.500
2	99.023	98.622	98.316	100.500	99.000	99.500
3	98.780	98.742	98.522	98.000	98.500	97.500
4	98.961	98.560	98.653	100.170	98.000	97.500
5	98.628	98.717	98.732	99.000	99.000	99.000

Independent preparations

- → Confirmed that one batch was tested in the study.
- → More information on testing obtained.
- → Each of the 6 runs is a repeatability assessment.
- → Useful to consider summary statistics for each run.

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Results:

(% Label Claim)

		Sending Unit			Receiving Unit		
		Analyst 1 Day 1 Run 1	Analyst 2 Day 1 Run 2	Analyst 2 Day2 Run 3	Analyst 3 Day 1 Run 4	Analyst 4 Day 1 Run 5	Analyst 4 Day 2 Run 6
Independent preparations	1	98.641	98.711	98.986	99.000	99.000	98.500
	2	99.023	98.622	98.316	100.500	99.000	99.500
	3	98.780	98.742	98.522	98.000	98.500	97.500
	4	98.961	98.560	98.653	100.170	98.000	97.500
	5	98.628	98.717	98.732	99.000	99.000	99.000
Mean		98.81	98.67	98.64	99.33	98.70	98.40
Standard deviation		0.16	0.07	0.22	0.90	0.40	0.80
%RSD		0.16	0.07	0.23	0.91	0.41	0.81

→ The means look similar, but variability is different between the two laboratories.

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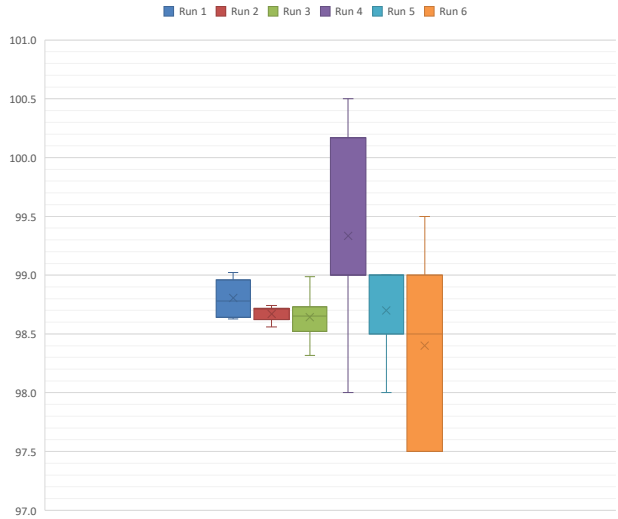
Box and Whisker Plot:



Box: Represents the middle 50% of the data (from the first quartile Q1 to the third quartile Q3).
Median Line: A line inside the box indicates the median value of the dataset.
Whiskers: Lines extending from the box show variability outside the upper and lower quartiles.
Outliers: Data points outside the whiskers are plotted individually as outliers.

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Results:

(% Label Claim)

		Sending Unit			Receiving Unit		
		Analyst 1	Analyst 2	Analyst 2	Analyst 3	Analyst 4	Analyst 4
		Day 1	Day 1	Day2	Day 1	Day 1	Day 2
		Run	Run	Run	Run	Run	Run
		1	2	3	4	5	6
Independent preparations	1	98.641	98.711	98.986	99.000	99.000	98.500
	2	99.023	98.622	98.316	100.500	99.000	99.500
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Standard deviation		0.16	0.07	0.22	0.90	0.40	0.80
%RSD		0.16	0.07	0.23	0.91	0.41	0.81

→ Useful to compare the results from the two laboratories.

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Results:

(% Label Claim)

		Sending Unit			Receiving Unit		
		Analyst 1	Analyst 2	Analyst 2	Analyst 3	Analyst 4	Analyst 4
		Day 1	Day 1	Day2	Day 1	Day 1	Day 2
		Run	Run	Run	Run	Run	Run
		1	2	3	4	5	6
Independent preparations	1	98.641	98.711	98.986	99.000	99.000	98.500
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Mean:	**SU**	98.71			**RU**	98.81		
95% CI of mean:	**SU**	98.60	to	98.81	**RU**	98.34	to	99.29
Standard deviation:	**SU**	0.18			**RU**	0.86		
95% Upper confidence limit of standard deviation:	**SU**	0.29			**RU**	1.36		
%RSD:	**SU**	0.19			**RU**	0.87		
95% Upper confidence limit of %RSD:	**SU**	0.30			**RU**	1.37		

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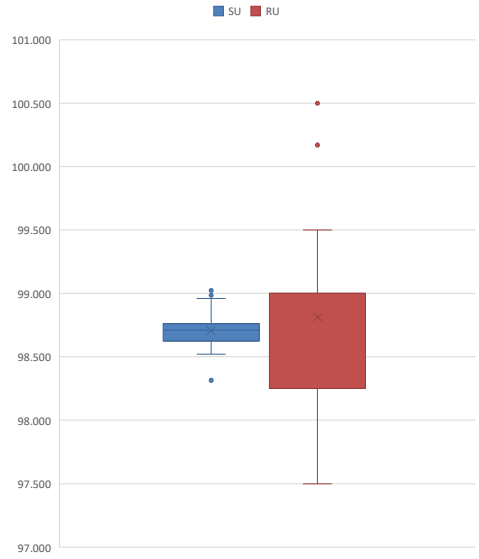
Box and Whisker Plot:



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Results:

(% Label Claim)

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Standard deviation:	**SU**	0.18			**RU**	0.86		
95% Upper confidence limit of standard deviation:	**SU**	0.29			**RU**	1.36		
%RSD:	**SU**	0.19			**RU**	0.87		
95% Upper confidence limit of %RSD:	**SU**	0.30			**RU**	1.37		
Difference between RU & SU		0.11						

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Results:

(% Label Claim)

		Sending Unit			Receiving Unit		
		Analyst 1 Day 1 Run 1	Analyst 2 Day 1 Run 2	Analyst 2 Day2 Run 3	Analyst 3 Day 1 Run 4	Analyst 4 Day 1 Run 5	Analyst 4 Day 2 Run 6
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Standard deviation:	**SU**	0.18			**RU**	0.86		
95% Upper confidence limit of standard deviation:	**SU**	0.29			**RU**	1.36		
%RSD:	**SU**	0.19			**RU**	0.87		
95% Upper confidence limit of %RSD:	**SU**	0.30			**RU**	1.37		
Difference between RU & SU		0.11						
95% CI of difference		-0.28	to	0.49				

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Confidence Interval Approach for TOST

→ Calculated for the difference in means and compared to the limits, θ_L & θ_U.

$$CI = \left(\bar{x}_{SU} - \bar{x}_{RU}\right) \pm t_{0.10(n_{SU}+n_{RU}-2)} s_p \sqrt{\frac{1}{n_{SU}} + \frac{1}{n_{RU}}}$$

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Conclusions:

- → The presentation of the data is different in terms of significant figures.
- → Is this what has caused the clear difference in terms of variability between the two laboratories, or is it something else?
- → The practical relevance of the difference is not significant, indicating that the method appears to be performing adequately in the RU.

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Learning Points:

- → It is very important to consider the use of significant figures and rounding when planning a method transfer study.
  - Want to compare 'like with like'
- → Essential to know exactly how data has been generated,
  - e.g., the use of replicates and the batch tested
- → The visualisation of data is very useful,
  - e.g., box and whisker plots
- → Practical relevance of any differences observed should be assessed carefully.

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CASE STUDY 2

METHOD: Determination of Impurity A in drug product (capsules)

A set of 6 results was generated in each of two laboratories for the transfer

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Results:

(% w.r.t. drug content)

	Impurity A		
	SU	RU	Ratio SU/RU (%)
1	0.281	0.258	91.6
2	0.317	0.272	96.7
3	0.294	0.270	95.8
4	0.301	0.264	94.0
5	0.292	0.276	98.3
6	0.295	0.257	91.5
AVG	0.30	0.27	94.6
SD	0.01	0.01	2.75
%CV	4.03	2.91	2.91

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Results:

(% w.r.t. drug content)

Impurity A

	SU	RU	Ratio SU/RU (%)
1	0.281	0.258	91.6
2	0.317	0.272	96.7
3	0.294	0.270	95.8
4	0.301	0.264	94.0
5	0.292	0.276	98.3
6	0.295	0.257	91.5
AVG	0.30	0.27	94.6
SD	0.01	0.01	2.75
%CV	4.03	2.91	2.91

→ Are sample 1 from SU and sample 1 from RU paired?

→ This is probably unlikely in method transfer by comparative testing

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Results:

(% w.r.t. drug content)

Impurity A

	SU	RU
1	0.281	0.258
2	0.317	0.272
3	0.294	0.270
4	0.301	0.264
5	0.292	0.276
6	0.295	0.257
AVG	0.30	0.27
SD	0.01	0.01
%CV	4.03	2.91

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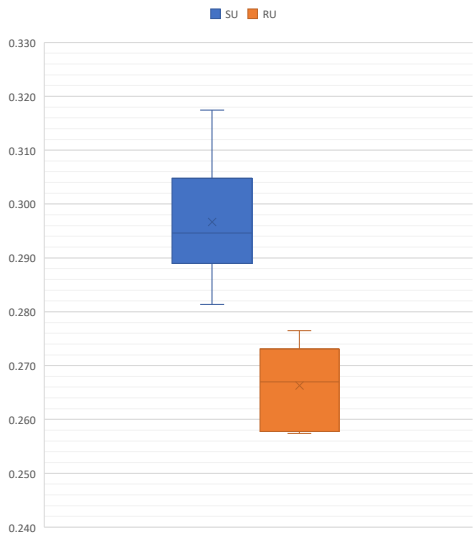
Box Plot



MTS

Results:

(% w.r.t. drug content)

Impurity A

	SU	RU
1	0.281	0.258
2	0.317	0.272
3	0.294	0.270
4	0.301	0.264
5	0.292	0.276
6	0.295	0.257
AVG	0.30	0.27
SD	0.01	0.01
%CV	4.03	2.91

Difference 0.03

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Results:
(% w.r.t. drug content)

Impurity A

	SU	RU
1	0.281	0.258
2	0.317	0.272
3	0.294	0.270
4	0.301	0.264
5	0.292	0.276
6	0.295	0.257
AVG	0.30	0.27
SD	0.01	0.01
%CV	4.03	2.91

Difference	0.03		
95% Confidence interval of difference	0.02	to	0.04

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Learning Points:

→ Assessment of comparative data requires care regarding what is compared to what.

→ A bias between the data obtained from two laboratories needs to be considered in the context of the requirements of the method.

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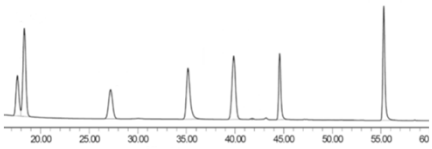
CASE STUDY 3

METHOD: Determination of an impurity in drug product (tablets)

A set of 12 results was generated in each of two laboratories for the transfer



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Results:

(% w.r.t. drug content)

	Sending Unit		Receiving Unit	
Sample	**Day 1**	**Day 2**	**Day 1**	**Day 2**
1	0.35	0.34	0.32	0.36
2	0.33	0.35	0.35	0.36
3	0.34	0.34	0.28	0.32
4	0.33	0.34	0.33	0.35
5	0.32	0.35	0.36	0.38
6	0.33	0.33	0.39	0.40

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Results:

(% w.r.t. drug content)

	Sending Unit		Receiving Unit	
Sample	**Day 1**	**Day 2**	**Day 1**	**Day 2**
1	0.35	0.34	0.32	0.36
2	0.33	0.35	0.35	0.36
3	0.34	0.34	0.28	0.32
4	0.33	0.34	0.33	0.35
5	0.32	0.35	0.36	0.38
6	0.33	0.33	0.39	0.40
Mean	0.33	0.34	0.34	0.36
Standard Deviation	0.01	0.01	0.04	0.03
%RSD	3.10	2.20	11.12	7.50

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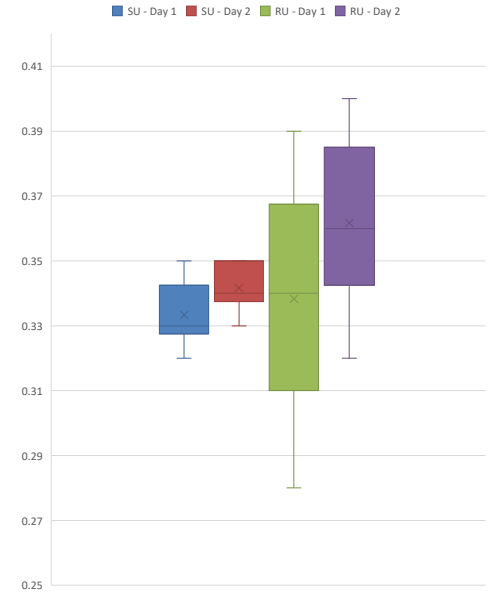
Box and Whisker Plot:



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Results:
(% w.r.t. drug content)

	Sending Unit		Receiving Unit	
Sample	**Day 1**	**Day 2**	**Day 1**	**Day 2**
1	0.35	0.34	0.32	0.36
2	0.33	0.35	0.35	0.36
3	0.34	0.34	0.28	0.32
4	0.33	0.34	0.33	0.35
5	0.32	0.35	0.36	0.38
6	0.33	0.33	0.39	0.40
Mean	0.33	0.34	0.34	0.36
Standard Deviation	0.01	0.01	0.04	0.03
%RSD	3.10	2.20	11.12	7.50

Mean:	**SU**	0.34			**RU**	0.35		
95% CI of mean:	**SU**	0.33	to	0.34	**RU**	0.33	to	0.37
Standard deviation:	**SU**	0.01			**RU**	0.03		
95% Upper confidence limit of standard deviation:	**SU**	0.02			**RU**	0.06		
%RSD:	**SU**	2.86			**RU**	9.59		
95% Upper confidence limit of %RSD:	**SU**	4.86			**RU**	16.29		

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Results:
(% w.r.t. drug content)

	Sending Unit		Receiving Unit	
Sample	**Day 1**	**Day 2**	**Day 1**	**Day 2**
1	0.35	0.34	0.32	0.36
2	0.33	0.35	0.35	0.36
3	0.34	0.34	0.28	0.32
4	0.33	0.34	0.33	0.35
5	0.32	0.35	0.36	0.38
6	0.33	0.33	0.39	0.40
Mean	0.33	0.34	0.34	0.36
Standard Deviation	0.01	0.01	0.04	0.03
%RSD	3.10	2.20	11.12	7.50

Mean:	**SU**	0.34			**RU**	0.35		
95% CI of mean:	**SU**	0.33	to	0.34	**RU**	0.33	to	0.37
Standard deviation:	**SU**	0.01			**RU**	0.03		
95% Upper confidence limit of standard deviation:	**SU**	0.02			**RU**	0.06		
%RSD:	**SU**	2.86			**RU**	9.59		
95% Upper confidence limit of %RSD:	**SU**	4.86			**RU**	16.29		

→ For an impurity at this level, this %RSD value may be above the acceptance criteria typically applied for intermediate precision.

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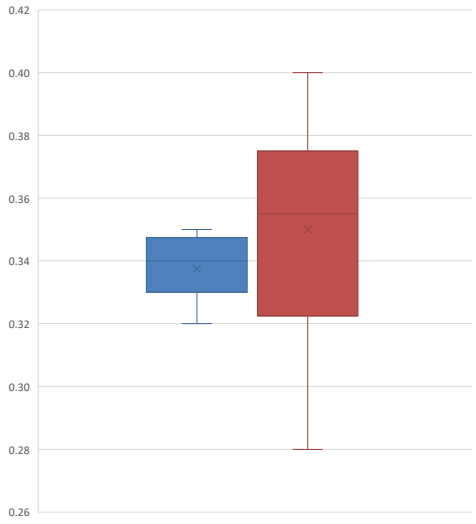
Box and Whisker Plot:



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Results:
(% w.r.t. drug content)

	Sending Unit		Receiving Unit	
Sample	**Day 1**	**Day 2**	**Day 1**	**Day 2**
1	0.35	0.34	0.32	0.36
2	0.33	0.35	0.35	0.36
3	0.34	0.34	0.28	0.32
4	0.33	0.34	0.33	0.35
5	0.32	0.35	0.36	0.38
6	0.33	0.33	0.39	0.40
Mean	0.33	0.34	0.34	0.36
Standard Deviation	0.01	0.01	0.04	0.03
%RSD	3.10	2.20	11.12	7.50

Mean:	**SU**	0.34				**RU**	0.35		
95% CI of mean:	**SU**	0.33	to	0.34		**RU**	0.33	to	0.37
Standard deviation:	**SU**	0.01				**RU**	0.03		
95% Upper confidence limit of standard deviation:	**SU**	0.02				**RU**	0.06		
%RSD:	**SU**	2.86				**RU**	9.59		
95% Upper confidence limit of %RSD:	**SU**	4.86				**RU**	16.29		
Difference between RU & SU		0.01							

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Results:
(% w.r.t. drug content)

	Sending Unit		Receiving Unit	
Sample	**Day 1**	**Day 2**	**Day 1**	**Day 2**
1	0.35	0.34	0.32	0.36
2	0.33	0.35	0.35	0.36
3	0.34	0.34	0.28	0.32
4	0.33	0.34	0.33	0.35
5	0.32	0.35	0.36	0.38
6	0.33	0.33	0.39	0.40
Mean	0.33	0.34	0.34	0.36
Standard Deviation	0.01	0.01	0.04	0.03
%RSD	3.10	2.20	11.12	7.50

Mean:	**SU**	0.34			**RU**	0.35		
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%RSD:	**SU**	2.86			**RU**	9.59		
95% Upper confidence limit of %RSD:	**SU**	4.86			**RU**	16.29		
Difference between RU & SU		0.01						
95% CI of difference		-0.01	to	0.03				

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Learning Point:

→ Practical relevance of any differences observed should be assessed carefully.

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CASE STUDY 4

METHOD: Determination of Impurity A, B, C and D in drug product (capsules)

A set of 5 results was generated in each of two laboratories for the transfer

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Results:

Impurity A		Impurity B		Impurity C		Impurity D		Any Individual Unspecified Impurity		Total Impurities	
SU	RU	SU	RU	SU	RU	SU	RU	SU	RU	SU	RU
ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND

→ None of the impurities were present in the sample chosen for the transfer study!

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Learning Points:

→ Samples for comparative studies need to be selected with care, particularly for impurity methods.

→ The analyte needs to be present in the sample!

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CASE STUDY 5

METHOD: Assay and impurities determination in drug product by HPLC (gradient elution)

RU unable to achieve the required value of plate count, N, in the method SST – transfer failed

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Background Information

$$\text{Plate count, } N = 16 \left(\frac{t}{W}\right)^2$$

→ During gradient elution, peak width remains constant due to the application of the gradient across each peak.

→ The value of N appears to increase with increasing retention times.

→ N is an inappropriate acceptance criterion for gradient HPLC methods.

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Cause of problem

→ The dwell volume on the HPLC system at the SU and that at the RU differed.

→ The effect of this was to change the retention time, t.

→ When W (peak width) remains constant, t determines the value of N.

→ Dwell volume needs to be addressed during transfer but also system suitability criteria should be appropriate.

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HPLC Dwell Volume

→ Applies to gradient HPLC methods.

→ No problem if a single system is used for the method, or the same model of HPLC system (assuming no configuration changes).

→ Transfer to different systems *may* be problematic, and compensation is sometimes possible.

→ Multi-linear gradients may be particularly difficult to transfer.

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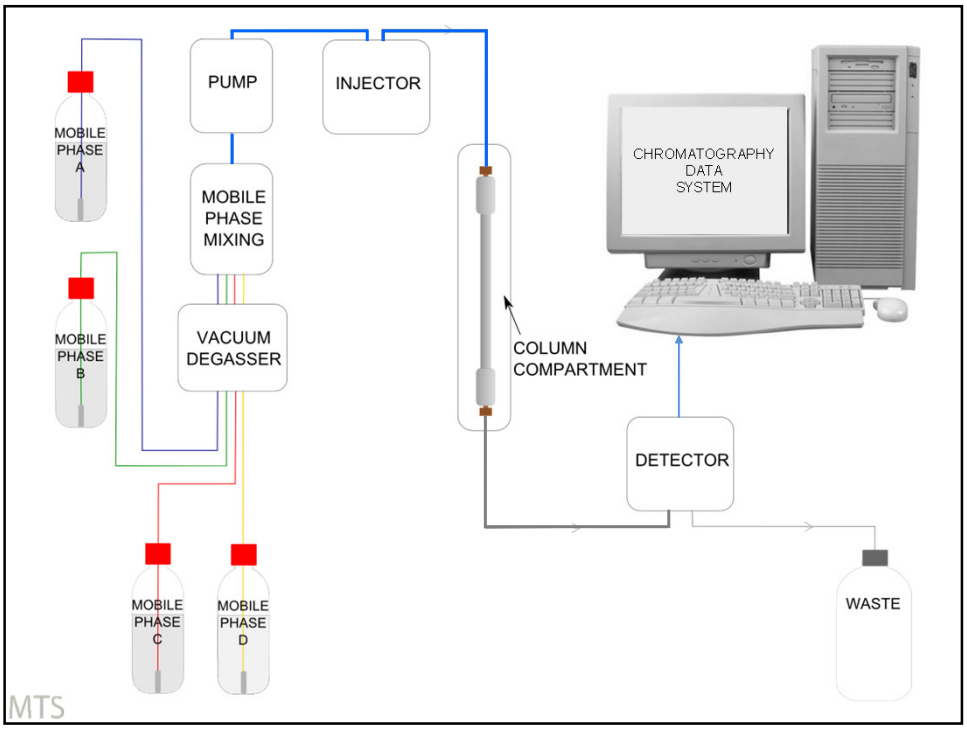

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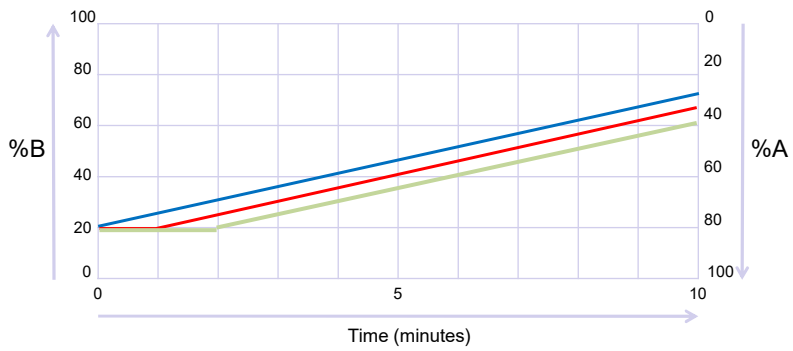

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Learning Points:

→ Knowledge and understanding of technology used in method is critical for successful transfer.

→ Appropriate acceptance criteria in both methods and transfer are required.

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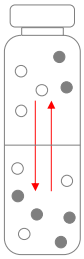
CASE STUDY 6



METHOD: Determination of residual methanol in tablets by GC-Headspace

Results at SU and RU are not in agreement

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Background

→ Analytical method is used to test for residual methanol since it is used in the tablet manufacturing process.

→ The test method involves using a ball mill to reduce the particle size of the tablet and thus achieve dissolution of the sample for the test.

→ The mill instruments at each site are different and thus it is thought that this is what is causing the difference in the results.

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Proposed Solution:

The instrument settings at the RU should be adjusted to achieve data which matches the SU results and thus the transfer study will pass.

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Analysis of Volatiles

→ Sample preparation is critical to ensure volatiles are not lost prior to measurement.

→ Manipulation of samples to make them suitable for analysis should not change the result!

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Learning Points:

→ The underlying principle of the analytical method needs to be scientifically valid.

→ Adjustments to 'make a transfer work' need to be very carefully considered.

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Summary of Learning Points from the Case Studies:

→ It is essential to plan exactly how data will be generated and how it will be compared.

→ Consider the use of significant figures and rounding when planning a method transfer study.

→ Suitable visualisation of data is very useful.

→ Practical relevance of any differences observed should be assessed carefully.

→ Samples for comparative studies need to be selected with care, particularly for impurity methods.

→ Knowledge and understanding of the technology used in method is critical for successful transfer and the underlying principle of the method needs to be scientifically valid.

→ Appropriate acceptance criteria are required.

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Analytical Method Transfer Success

Key to successful transfer is method knowledge and understanding:

→ Thorough evaluation of the method involving SU & RU

→ Comprehensive training/familiarisation for the RU on the new method.

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Analytical Method Transfer Success

Good communication between SU and RU is critical:

→ Communicate early in the process and frequently,

→ Single lead contact at each site,

→ Face to face meetings preferable,

→ Experienced analyst from SU at RU during transfer is a good idea.

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Thank you

ANY QUESTIONS?

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