



# Underlying Benefits of Working Groups

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- **Case Study Title:** Underlying Benefits of Working Groups
- **Working Group:** Data Integrity
- **Opportunity Identified:** Expansion of DI knowledge

## Introduction

The topic of Data Integrity has been an interest of mine for many years, likely due to my analytical background. While my practical knowledge was really focused on QC, as an auditor for our company I wished to expand that knowledge beyond just QC. The opportunity to participate in the Rx-360's Data Integrity Working Group was given to me several years ago and seemed to provide me with the potential to expand my knowledge.

## Conclusion

The time spent with the Rx-360 DI Working Group has been valuable in aspects beyond what I originally considered. We worked to create the GMP Audit Manual for Data Governance and Data Integrity which took about a year of contributing/editing. These discussions led a deeper understanding of other DI relevant areas including CSV, manufacturing and use of service groups like Software as a Service (SaaS).

The topic of Data Integrity continues to be at the forefront of topics within the Pharma industry. Participation in the Data Integrity working group has allowed for both sharing of best practices during the development of the guidance, but more importantly has helped build lasting relationships with other participants in the team.

As our company continues to develop our DI program, this team participation has allowed for valuable benchmarking from other companies before putting processes in place. Regulations tell us what to do but most often not how to comply so sharing is essential. I can say only positive things about both the participants and host(s) of our working group. Looking forward to finalize our next document within the DI Working Group in the near future.