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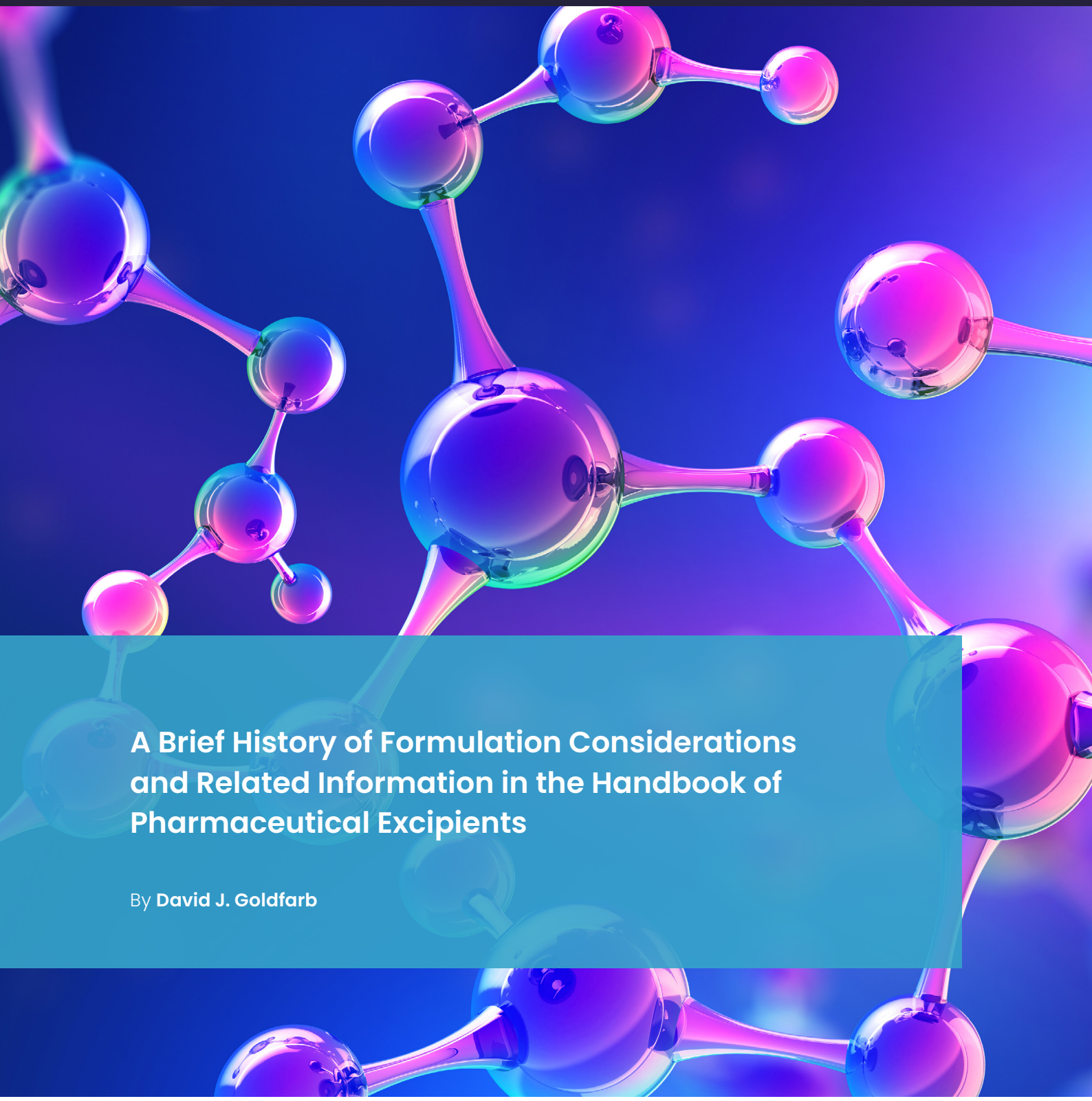

A Brief History of Formulation Considerations and Related Information in the Handbook of Pharmaceutical Excipients

By **David J. Goldfarb**

A one stop guide to the properties for excipients, their safe use and application

Pharmaceutical Excipients

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Introduction

The first seven editions of the Handbook of Pharmaceutical Excipients consisted primarily of excipient monographs. Though the number of monographs grew nearly three-fold from the first to the seventh edition, another area of growth was explored at the ISC (International Steering Committee) meeting of the Handbook in November 2014: to add "general chapters/practical guides/commentaries" to the next (eighth) edition. There was consensus that this was a valuable area of growth for the Handbook, with particular enthusiasm for the idea of adding a chapter on excipients in pediatric formulations.

The editors, with help from ISC members, selected four topics and identified authors for each of these guidance chapters, which were published in the eighth edition in 2017. In addition to a chapter on formulating pediatric dosage forms, three others were included: a chapter on functional categories of excipients, which contains a table comparing these categories as they are

An excerpt from 'A Brief History of Excipients', a chapter addition to the ninth edition of the Handbook.

For the ninth edition, chapters covering topics such as the use of counter-ions and co-formers in the creation of salt and co-crystal forms of APIs, and a brief history were also included providing the Handbook with more holistic support on wider formulation considerations

used in the Handbook and the USP-NF (General Chapter <1059> Excipient Performance); a chapter on reactive components in excipients (akin to the degradation products monitored in active pharmaceutical ingredients (API)); and, finally, a chapter on excipient selection for oral solid dosage forms.

The latter chapter was seen as a launching point for a suite of chapters on excipient selection for other dosage forms. In the just published ninth edition (2020), two more chapters were included in this vein, with injectable and orally inhaled dosage forms support added. Similar to the extension of API notions to excipients in the area of reactive components (e.g., degradation), the absorption, distribution, metabolism, and excretion (ADME) properties of excipients are explored in a chapter on the biological effects of excipients.

For the ninth edition, a decision was made to also include chapters covering topics towards the periphery of the Handbook scope, such as the use of counter-ions and co-formers in the creation of salt and co-crystal forms of APIs, and a brief history — of excipients, of course. These resources allow the Handbook to provide more holistic support on wider formulation considerations.

TABLE 1

General chapters in the Handbook of Pharmaceutical Excipients ninth edition

Number	Chapter	Authors
1	Functional Categories of Pharmaceutical Excipients	DJ Goldfarb, X He, CC Sun
2	Pharmaceutical Excipients in Pediatric Formulations	L Contreras, A Cram, C English, J Heimlich
3	The Selection of Excipients for Oral Solid Dosage Forms	IL Smales, MG Rowland
4	The Selection of Excipients for Injectable Formulations	WJ Lambert
5	Formulation Considerations for Orally Inhaled Dosage Forms	JG Clarke, ML Dawson
6	Reactive Components in Pharmaceutical Excipients	R Chen, BC Hancock
7	Biological Effects of Pharmaceutical Excipients	S Apte, N Petrovsky
8	The Use of Counter-ions and Co-formers in the creation of salt and co-crystal forms of Active Pharmaceutical Ingredients (API)	BC Hancock
9	A Brief History of Excipients	BC Hancock, RC Rowe

All the chapters appearing in the ninth edition are listed in Table 1. For the next edition, and ongoing digital updates, we plan to further expand this section of the Handbook. The chapters are a valuable tool that enables the Handbook to address developments within the field beyond the scope of any individual excipient. The Editors welcome ideas for additional Formulation Considerations and Related Information which can guide the pharmaceutical scientist.

Pharmaceutical Excipients

Featuring practical chapters on excipient considerations for different dosage forms, and uniform excipient records detailing functional categories and property data, Pharmaceutical Excipients is essential for those involved in the development, production, control, or regulation of pharmaceutical preparations.

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